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<b>13. SUPPLEMENTARY NOTES</b>				
<b>14. ABSTRACT</b> The overarching goal of the BADER Consortium is to advance and strengthen evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for each wounded warrior. This will be accomplished by advancing each of the following strategic areas: 1: Strengthen and support orthopaedic rehabilitation research capabilities through infrastructures and partnerships; 2: Conduct a variety of innovative, high impact, and clinically relevant research studies; 3: Establish a self-sustaining research enterprise by broadening the scope of impact and support for the BADER Consortium. <b>Key Accomplishments to date:</b> Established: Administrative Core, Clinical Research Core and Scientific Technical Cores; approval and establishment of five clinical research projects; development and implementation of an Omnibus CRADA; established a consortium-wide omnibus PDMS; partnership with the DoD and VA's Extremity Trauma and Amputation Center of Excellence (EACE); developed research focus (gap) areas in partnership with EACE; established and implemented a complete process for the call, submission, review and selection of Consortium funded projects; published the annual BADER call for clinical research proposals, established the BADER Consortium SOPs; completed the hiring of eight research support staff to be placed onsite at MTFs; established partnerships with the VA and NIH; obtained \$4M of external funding				
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## Introduction

### The BADER Consortium

The **overarching goal** of the BADER Consortium is to Bridge Advanced Developments for Exceptional Rehabilitation. The omnibus consortium model system, as opposed to a project centric model, focuses on the rapid forming and execution of many projects within broad research initiative areas. It avails to investigators unique human resources recruitment processes, incorporates innovative strategies including an omnibus CRADA and is uniquely suited to being a vehicle for technology companies to propose clinical trials for highly advanced technologies. The BADER Consortium is a multi-institutional Consortium that works in concert and partnership with military Medical Treatment Facilities (MTFs), Veteran's Affairs Centers, Academic and Industry leaders to conduct innovative, high-impact, clinically relevant research to further strengthen evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for each wounded warrior.

The success of the Consortium relies on strong partnerships with military Medical Treatment Facilities, the VA and non-government entities in each of the following strategic areas to:

1. Strengthen and support orthopaedic rehabilitation research capabilities:
  - infrastructures and cultures
  - partnerships
2. Conduct a variety of innovative, high impact, and clinically relevant research studies
3. Establish a self-sustaining research enterprise
  - Broaden the scope of impact and support for the BADER Consortium

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If developing research cooperation between a civilian organization and a government agency is considered by most to be a challenging endeavor, establishing an effective and dynamic research Consortium across multiple agencies, academic centers, and industrial leaders would be considered daunting. To tackle this task, the BADER Consortium has established a series of model omnibus administrative and research tools and standard operating procedures. Fundamentally, these tools and associated policies and procedures support partnership building, streamline the project initiation process, strengthens the project execution phase, enhances the scope and impact of research while ensuring protection of critical assets such as the US Governments rights to intellectual property and data, patient confidentiality, and protection of human subjects.

This report describes how the BADER Consortium has made progress based on the approved Statement of Work for the period September 29, 2011 – September 28, 2013.

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## Research accomplishments to date based on Statement of Work

### Administrative Core:

#### **Task 1: Financial Support and Oversight:**

- 1a. Provide oversight of the overall Consortium budget including auditing for allowable expenses, managing re-budget requests and preparing all required financial reports – months 1-60
- 1b. Ensuring all Military Treatment Facilities (MTFs) receive infrastructure support as required including procurement of materials, personnel, equipment – months 1-60
- 1c. Manage costs supporting the Cores and Clinical Study Sites – months 1-60
- 1d. Perform quarterly financial audits for compliance – months 1-60
- 1e. Maintain files for internal or external audit purposes – months 1-60

- Quarterly financial audits of the BADER Consortium have had no significant findings.
- Spending is behind due to delays in receiving administrative approvals, hiring support staff and a slower than anticipated spending rate of subcontracts. In addition, a major expense originally budgeted for the first year did not occur due to a much less expensive alternative to the originally proposed protocol and data management system.
- Identification of cost savings and efficiencies in year 1 and year 2 allowed for an increase in the budget available to fund research projects for the first Call for Proposals from an originally proposed \$2.7M to \$4.5M.
- In March 2013, the Government Steering Committee (GSC) recommended funding \$5.8M worth of proposals from the first Call for Proposals; however the budget available for research projects was limited to \$4.5M. The three Investigators whose projects were selected for funding successfully reduced their project budgets, resulting in a total of \$4.41M, \$87k under the target of \$4.5M. The remaining \$87k will be transferred to the next Call for Proposal budget.
- Procurement of furniture was provided for the UD personnel located at the Center for the Intrepid pursuant to request from the MTF representative. This was approved in advance by Mr. Chris Baker, Contract Specialist. In addition, all Clinical Research Core (CRC) staff received the computer and printer support deemed necessary by their MTF representatives.
- In the summer of 2013, the BADER award was selected for audit through random sampling by the external auditors for the University of Delaware. At the time of this report, we have not been notified of any audit findings and do not expect to have any findings.
- Complete and accurate files have been kept for internal and external auditing purposes.

**Task 2: Human Resources Support and Oversight**

- 2a. Manage Human Resources function including recruitment, on-boarding, facility/system access, annual performance appraisals, and handling benefits questions – months 1-60
  - 2b. Provide support as needed for labor relations actions – months 1-60
  - 2c. Manage payroll function for UD employees (at UD and MTF sites) – months 6-60
  - 2d. Work with Steering Committee to develop appropriate job descriptions – months 1-3
  - 2e. Manage recruitment activities of personnel – months 1-60
- MTF and BADER leadership worked collectively to develop model staffing plans that incorporate and complement BADER Consortium, Extremity Trauma and Amputation Center of Excellence (EACE) and existing MTF resources. The MTF representatives at each site have been actively engaged in the search process for all staff positions including development of position descriptions, interviews of applicants and final selection.
  - To meet MTF needs, some of the position descriptions and titles changed slightly from the original proposal. We successfully recruited on-site staff at each MTF to meet the needs expressed by MTF representatives to strengthen their research infrastructures.

Table 1: Summary of recruitment activity over the first two years of performance:

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Position	Location	Date Filled	Current Status
Director, Administrative Core	University of Delaware	January 2012	Filled, full-time
Manager, Clinical Research Core	University of Delaware	September 2012	Filled, part-time
Administrative Assistant	University of Delaware	October 2013	Filled, full-time
Administrative Assistant	Spaulding Rehabilitation	July 2013	Filled, part-time
Research Associate	WRNMMC	January 2013	Filled, full-time
Research Associate	NMCSD	June 2013, resigned Sept 2013	Vacant
Research Associate	NMCP	June 2013	Filled, full-time
Research Associate	BAMC/CFI	November 2012, reassigned Nov 2013	Vacant
Protocol and Data Coordinator	WRNMMC	January 2013	Filled, full-time
Protocol and Data Coordinator	NMCSD	December 2012	Filled, full-time
Protocol and Data Coordinator	NMCP	February 2013	Filled, full-time
Protocol and Data Coordinator	BAMC/CFI	November 2012, resigned Sept 2013	Vacant

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*Notes on staffing:*

- **Manager, Clinical Research Core:** The current CRC manager is working at 25% capacity and this effort has been successful to date. We will look to shift some of these responsibilities to the Director of Research as the next round of research projects are awarded and the pre-award/call for proposal related functions at Spaulding are no longer needed.
- **Administrative Assistant:** A new Administrative Assistant to the Consortium Director at UD started on October 7, 2013 replacing the Assistant that resigned at the end of July.
- **Research Associates –** In Year 2, all four positions were filled. However, at the end of Year 2, we received a resignation notice from the Research Associate at Naval Medical Center San Diego (NMCSD). We will work with the MTF representative at NMCSD, Marilyn Wyatt, to refine the job description and begin recruitment activity to fill the vacancy. Effective November 1, 2013, the Research Associate relocated from Brooke Army Medical Center (BAMC) to Spaulding Rehabilitation Hospital at Boston (Spaulding). At this time, the MTF Representative at BAMC/CFI, Jason Wilken, is developing an alternative resource utilization plan.
- **Protocol and Data Coordinators –** In Year 2, all four positions were filled. At the end of Year 2, we received a resignation notice from the Research Protocol and Data Coordinator at BAMC. At this time, the MTF Representative at BAMC/CFI, Jason Wilken, is developing an alternative resource utilization plan.

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**Task 3: Reporting Coordination and Management:**

- 3a. Request, coordinate and submit all required technical reports – months 1-60
- 3b. Preparation of all required financial reports – months 1-60
- 3c. Develop templates for reports to ensure consistency – months 1-4
- Coordinated the compilation, editing and submission of all quarterly and annual reports.
- Oversaw the completion of the quarterly financial report. The quarterly financial reports as required by the award have been submitted on time.
- Created templates for quarterly reporting to ensure consistency.
- Developed and distributed over 150 copies of the glossy annual report to BADER affiliates, government representatives and other interested parties.

**Task 4: General Administrative Support:**

- 4a. Coordinate meetings, calendars, travel, etc. – months 1-60
- 4b. Facilitate communications across Consortium

- 4c. Prepare administrative documents – months 1-60
- 4d. Coordinate all official BADER correspondence – months 1-60

4a. Coordinate Meetings:

**Government Steering Committee (GSC) Meetings:**

- The first GSC meeting for the BADER Consortium was held January 12, 2012 in Fort Detrick, MD. This meeting convened the GSC and representatives from CDMRP, MTFs, and BADER Consortium, including those from the University of Delaware, Mayo Clinic, Spaulding Rehabilitation Hospital and the University of Texas Austin. The one day meeting provided attendees with an overview of the Consortium, a brief presentation and discussion of each of the four initially proposed research projects, a presentation of USAMRMC ORP oversight, a briefing on the August 2011 BADER Discovery trip, and a discussion of the proposed selection process for future research projects. The agenda and list of attendees is included in Appendix G.

Approvals and recommendations received from the meeting:

- Summary of recommendations on all four initially proposed research projects
  - General comments on the BADER Consortium
  - Recommendations on the study selection process and external peer review
- The second GSC meeting was held on March 18, 2013 at Fort Detrick, MD. Topics covered included the progress to date of the Consortium, perspectives from an MTR Representative, an update on the current studies, research project selection process and results, and the EACE perspective of current research focus areas. There was also a closed session for the GSC to deliberate on the seven research proposals in response to the Call for Proposals. Due to travel restrictions, many of the invitees participated via teleconference and DCO Connect. Despite the limitations of not being face-to-face, the meeting was very productive and well executed.

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The primary purpose and outcome of the meeting was the discussion and selection of the research proposals to be funded. Of the seven proposals under review, four were selected for funding:

Alena Grabowski, PhD. *“Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?”* Recommended for funding.

Alison Linberg, DPT. *“Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators.”* Recommended for funding with contingencies.

David Tulsy, PhD. *“Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma”* Recommended for partial funding with contingencies.



Kenton Kaufman, PhD. *“Bone Health and Fracture Risk in Warfighters with a Lower Extremity Amputation.”* Not recommended for BADER funding.

G. Kelley Fitzgerald, PhD. *“Rehabilitation of Post-Traumatic Stiffness in the Lower Extremity: A Proof of Concept Study.”* Not recommended for BADER funding.

Erik Wolf, PhD. *“The Role of Transient Locomotion Tasks in Development of Acute and Chronic Secondary Injury in those with Lower Extremity Trauma.”* Not recommended for BADER funding.

Jae Kun Shim, PhD. *“Innovative Methods to Remove Harmful Vibration in Running Specific Prostheses.”* Not recommended for BADER funding.

The agenda and list of attendees is included in Appendix G.

- The third GSC meeting is currently being planned for February 2014 at Fort Detrick, MD.

**BADER Consortium Annual Meeting:** The first WARRIOR (WARfighters Receiving Innovative Oртоpaedic Rehabilitation) Summit was held at BAMC on June 12, 2013. The agenda and list of attendees is included in Appendix H of this report. Topics covered included brief progress to date of the Consortium, mission and goals of EACE, BADER research directions, DoD rehabilitation research areas, development and prioritization of BADER research initiatives, and a discussion on sustainability. Due to travel restrictions and other reasons, five of the invitees participated via teleconference and DCO Connect. The IT and telecommunication infrastructures worked well and the meeting was very productive and well executed.

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The following research gap areas were identified and used in the second BADER Consortium Call for Proposals:

1. Determine factors that predict development and successful treatment of musculoskeletal conditions following severe extremity trauma and/or deployment-related musculoskeletal injuries.
2. Determine the optimal treatment strategies to minimize impairments, maximize function and performance, and/or achieve optimal quality of life.
3. Develop metrics that effectively quantify changes that result from rehabilitation or provision of novel technologies.

**2014 State of the Science Meeting:**

Planning is currently underway to participate in the International State of the Science Meeting on Limb Salvage in cooperation with the Department of Defense Blast Injury Research Program. Dr. Kaufman is representing BADER on the planning committee. This meeting is tentatively planned for January 14-15, 2014 at Fort Detrick, MD.

The objectives of the meeting are:

- i. Define Limb Salvage and identify/characterize the types of injuries that require limb salvage.
- ii. Identify existing technologies and interventions that are most commonly used in limb salvage.
- iii. Identify emerging technologies and interventions in limb salvage.
- iv. Identify what can be done in the near term to improve outcomes and the quality of life for Service members with limb injuries.

Additional information can be found

at: [https://blastinjuryresearch.amedd.army.mil/index.cfm?f=application.pco\\_sos\\_2013\\_limb\\_salvage](https://blastinjuryresearch.amedd.army.mil/index.cfm?f=application.pco_sos_2013_limb_salvage)

BADER Consortium Coordinating Center (B3C) meetings: Monthly meetings are held via conference call to continue the development and implementation of the BADER Consortium infrastructure. Various topics have included: the development of position descriptions for the Clinical Research Core, planning for participation in an annual scientific meeting; discussion of policies and procedures; updates on the feasibility study of the PDMS; updates from the Director of Research on the biweekly meetings with MTF representatives, among others. See Appendix I for composition of B3C.

BADER Consortium Committee (BCC) meetings: Monthly BCC meetings are held via teleconference to update Consortium members on BADER activities, receive updates from MTF representatives and Core Directors, problem solve and plan activities. A topic of recent interest from the MTF representatives the development and implementation of the human subject recruitment initiative in response to the declining number of injured soldiers returning from war. See Appendix I for composition of BCC.

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Annual Meeting: After a successful annual meeting in San Antonio in June 2013, plans are underway to hold a second annual orthopaedic rehabilitation meeting sponsored by the BADER Consortium and key strategic partners. The goal of the meeting will be to further coordinate research efforts and identify emerging research initiatives by fostering communication and networking among the orthopaedic rehabilitation community, Consortium investigators and administrative leaders of the BADER Consortium. The second annual meeting will address both the business and scientific aspects of the BADER Consortium. Approximately 50% of the meeting will focus on scientific presentations, as Principal Investigators receiving research support from the BADER Consortium will be asked to provide updates on their project status. The business aspect of the meeting will cover the following key areas:

- Update on BADER Consortium
- Executive Committee reports
- Scientific Core reports
- Establish current of standards for O & P measurements and standardization of data collection procedures
- Formation and operation of clinical trials
- Intellectual property
- Sustainability
- Cooperation and integration between the BADER Consortium and the EACE

- Establishment of yearly priorities

The venue for future Annual Meetings will change each year, rotating through all of the MTFs. This will provide opportunity for the clinicians at each MTF to participate in person, learn about the BADER Consortium, and help guide the translational aspects of the ongoing research to achieve optimal functional outcomes. In addition to the local clinicians, attendees will include Principal Investigators of all research projects, members of the BADER Consortium Coordinating Committee, External Advisory Committee, and individuals from CDMRP. The BADER Consortium Administrative Core has developed plans for establishing virtual meeting capabilities that will support remote participation in all aspects of the meeting. The meeting is currently being planned for June of 2014.

#### **4b: Facilitating Communications**

Communication among all members of the BADER Consortium community is vital to the efficient and effective implementation of large-scale rehabilitation research initiatives afforded through the BADER Consortium. The Administrative Core has worked diligently over the first two years to establish tools to allow researchers and administrative staff to communicate effectively, efficiently and without delay. Taking into consideration the need for secure communications, high video/audio quality, and ability to content-share, record and playback, all with ease-of-use and support, we make available low-cost, highly-effective communication tools to join our geographically dispersed entities.

Website ([bader-c.org](http://bader-c.org)): The BADER Consortium website has been enhanced over the first two years of performance by providing numerous resources for investigators and the community at large. Developing the secure log-in site has proved to be more difficult than originally anticipated; therefore, that feature will likely not be added to the website. The website currently features:

- Events calendar
- List of current BADER Consortium Affiliates (BCA)
- Application/policy to become a BCA
- Current Job postings
- News related to the Consortium and our partners
- Materials related to the request for proposals
- CRC description and staff contact and profile information
- Standardized forms for reporting
- List of Partners
- Information about Scientific Technical Cores (STC)
- Form to request STC services
- Standard operating procedures
- Links to useful reference materials
- Requests for Applications (RFAs) related to orthopaedic rehabilitation research from federal and non-federal agencies.
- Google Groups site was established to enable leadership to send out broad announcements to all of the BADER Consortium community.

A web developer has been hired to oversee the implementation of major enhancements to the website to be launched in the first quarter of year 3.

Real-time video collaboration: Due to IT security requirements at DoD sites and civilian clinical sites, it has been quite challenging to agree upon a solution that would allow for video and screen-sharing among Consortium members. With assistance of DoD's IT staff, we have been able to identify software and hardware solutions that will meet all parties' needs with minimal burden on staff at each site. Additional testing among sites is needed, but we are optimistic that our planned implementation will be successful. The solution will enable video communication in various scenarios: webinars, ad hoc videoconferences with up to three participating sites, and larger multi-site videoconferences for more than three sites.

Webinars will be enabled by Adobe Connect, or the DoD's secure equivalent, Defense Connect Online system.

Videoconferencing will use free or low-cost software (e.g., CISCO's Jabber/Movi, Logitech Softphone). DoD's USAMITC gatekeeper services will provide DoD participants additional security. If and when needed, we will purchase Logitech Conference Cams to provide small conference-room HD-video and speakerphone capabilities. Large flat-panel displays may complement other HD-quality displays. The University of Delaware will provide CISCO-based video-bridging services for videoconferences involving more than three sites. In all cases, meetings can be recorded and made available for playback.

Teleconference support: The University of Delaware has established three teleconference phone accounts that are available for use by all Consortium members.

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Travel authorization: In an effort to enhance research communications and collaborations, BADER received authorization to use Consortium funds to travel government officials for the purposes outlined under Task 5. To date, Consortium funds have supported two MTF researchers to attend national research conferences and plans are underway to support a VA researcher to travel to WRNMMC to discuss research collaborations.

Document Sharing: BADER staff have tested a variety of options for document sharing and has determined that the best approach is situational in nature. Therefore, we have found success in capitalizing on the variety of options presented across institutions. For example, CRC staff are able to access and share information with non-DoD individuals through the UD dropbox where as they are also able to access and share documents with DoD personnel via the DoD dropbox system. In some instances, we have been successful in using Google Drive for real-time document development. For other circumstances we have visually shared documents via Adobe Connect and/or DCO.

**Task 5: Policies and Procedures:**

- 5a. Develop, implement and ensure compliance of all SOPs for The BADER Consortium (months 1-60)
- 5b. Ensure compliance with all existing policies and procedures (months 1-60)

- 5c. Create a policy and procedure manual to be distributed to all BADER stakeholders (months 1-12)

Policies and Procedures: The SOPs for the BADER Consortium were established in 2012 and are considered a living document – to be reviewed annually and when necessary to maintain compliance with Federal, State and University regulations and to adapt to a changing conditions within and outside of the Consortium. The comprehensive document includes policies and procedures in the following areas:

- Governance
- Research Study Initiation and Implementation
- Data Management and Data Collection
- Quality Assurance and Quality Improvement
- Study Management and Monitoring
- Publications and Presentations
- Cooperative Research and Development Activities
- Clinical Site Performance
- Fiscal Management
- General administration

The SOPs are currently undergoing review and revisions at the start of year 3. Once completed, they will be posted to a secure area of the BADER website.

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BADER Consortium research-related travel policy: A policy that has been particularly well received by the MTFs is the policy pertaining to travel support for government officials. In response to current travel restrictions for government officials, BADER requested approval from the GO/GOR for approval to travel government officials for research and related purposes. Approval from CDMRP was received to travel government officials under the following policy:

*Policy 19.1: Within this award, the University of Delaware is authorized to cover travel cost associated with the Government/Military personnel providing research effort on this award. The specific language states:*

**9. TRAVEL-GOVERNMENT/MILITARY PERSONNEL (MARCH 2008) (USAMRAA)**

*Travel costs associated with the Government/Military personnel providing research effort on this award are authorized in accordance with Title 31 U.S.C. Section 1353.*

*Pursuant to this article in the cooperative agreement, the BADER Consortium wishes to utilize this authorization to use BADER Consortium funds for the types of travel listed below that fall under the general guidance of “providing research effort on this award.”*

*Therefore, the purpose of this policy to provide guidelines for travel of government/military personnel providing research effort affiliated with BADER Consortium activities using the following definitions:*



- 1) *a research site associated with the planning of a collaborative research project/protocol involving two or more study sites.*
- 2) *a research site associated with the execution of an active collaborative research project/protocol involving two or more study sites.*
- 3) *a meeting for research programmatic planning purposes and the development of research priority areas (gap areas).*
- 4) *travel to a scientific meeting for the purpose of actively presenting (i.e., poster, or oral presentation) scientific findings.*

Under our recently approved travel policy, BADER has provided travel support for two MTF personnel (Wilkens, CFI and Wolf, WRNMMC) to attend the American Society of Biomechanics meeting in September, 2013. Due to current government travel restrictions, MTF staff continue to request travel funds to attend scientific meetings. We have also received a request to travel Dr. Andrew Hansen (VA) to WRNMMC for Grand Rounds and a meeting with Dr. Erik Wolf regarding research collaborations between the VA and WRNMMC. The originally planned date was postponed due to the partial government shutdown and is currently being rescheduled.

**Task 6: Proposal/Award Coordination and Management:**

- 6a. Management of annual project solicitation process to BADER Affiliates – months 1-48
- 6b. Management of approved projects (financial, HR, administrative support) – months 13-60
- 6c. Oversight of all subawards for technical and financial compliance – months 1-60

- Year 3 subcontracts are delayed as we await completion of contract negotiations with the contract specialist.
- Subcontract budgets were analyzed for spending patterns at the end of year 2. Funds not spent during the first two years will be re-budgeted in the Consortium. The approximate amount will be: \$177,000.
- During year 2, quarterly finance audits revealed that two sub-awards under the Consortium over-billed for salaries for two months. The institutions were contacted and have corrected the invoices.
- Efforts are underway to subcontract the three research projects approved by the GSC (March 18, 2013) in the first Call for Proposal cycle. At this time, we are awaiting contact from CDMRP officials to the University of Delaware to complete negotiations.
- Key steps have been effectively managed in the Call for Proposals process, including the distribution of Research Advisory Committee findings, the preparation of reports to the GOR and the coordination of the GSC response process. A complete summary of Call for Proposal process is provided under the Clinical Research Core statement of work.

- As part of the management of approved projects, BADER has developed an SOP for rapid research implementation that supports Consortium investigator efforts to fully prepare to execute the protocol while awaiting necessary IRB/HRPO approvals. The Principal Investigator (PI) Research Agreement is a mechanism intended to bind a researcher to the fundamental policies of the Consortium and hold them accountable for research and reporting milestones. Upon execution of this agreement by a Principal Investigator, the Consortium issues a conditional subcontract that allows the PI to recruit research personnel, order equipment and supplies and begin research activities that do not involve human subjects. Once all IRB and final HRPO approvals are received, the PI receives a letter from the Consortium giving approval to move forward with human subject research activities.

**Task 7: Intellectual Property, Material Property, Inventions and Patents Management:**

- 7a. Management of IP, MP, Invention and Patent agreements – months 1-60  
7b. Consult with legal experts as necessary for compliance – months 1-60

Omnibus BADER CRADA: A common cause for delay in research conduct is the creation and negotiation of Cooperative Research and Development Agreements (CRADAs) between agencies and other research entities. In an effort to reduce this administrative delay and streamline the CRADA approval process, members of the BADER Administrative Core developed a model omnibus CRADA (BADER CRADA). The BADER CRADA provides a unique procedure that allows the Consortium to rapidly 'onboard' individual entities into a single cooperative research and development agreement with the University of Delaware that covers general BADER Consortium activities. Research project-specific activities and their details may be added to the omnibus CRADA as addenda. The BADER CRADA provides a standard operating procedure that addresses the issues of intellectual property, publications, data sharing, subject inventions and licensing among all CRADA parties. With support and guidance from the Chief, Medical Research Law, Office of the Staff Judge Advocate, U.S. Army Medical Research and Materiel Command, the BADER CRADA was finalized and distributed to all current partner organizations in early September 2012.

The omnibus BADER CRADA has been accepted by all Consortium partners with the exception of the two Naval sites. To date, seven of the initial ten partnering institutions have been on-boarded to the BADER CRADA (see Table 2 below). With the recent GSC research project recommendations (three new approved projects), the BADER CRADA will be implemented at several new sites – including our first VA research site. Efforts to obtain Navy's approval of the BADER CRADA continue.

Table 2: List of current and pending BADER CRADA partners

Institution	Date of distribution	Date of completed agreement
University of Delaware	September 19, 2012	November 7, 2012
Brooke Army Medical Center	September 19, 2012	January 3, 2013
C-Motion, Inc	September 19, 2012	September 20, 2012
Christiana Care Health Systems	September 19, 2012	October 18, 2012
Mayo Clinic	September 19, 2012	November 1, 2012

Spaulding Rehabilitation Hospital	September 19, 2012	October 11, 2012
University of Michigan	September 19, 2012	Cancelled (Tulsky relocated)
Naval Medical Center San Diego – omnibus CRADA	September 19, 2012	Rejected
Naval Medical Center Portsmouth – omnibus CRADA	September 19, 2012	Rejected
Walter Reed National Military Medical Center	September 19, 2012	April 15, 2013
New York University (for Tulsky Core services)	To be distributed soon	Pending distribution
Virginia Commonwealth University	September 2013	Pending UD signatures
Naval Medical Center Portsmouth – project specific	September 19, 2013	Pending UD signatures
Naval Medical Center San Diego – Project specific	Awaiting CRADA from NMCS D	
Denver Research Institute (Grabowski project)	September 2013	Pending review at DRI
Walter Reed National Military Medical Center (amendment to add Linberg project)	Not distributed yet	Pending approval of contract negotiations from CDMRP Contract Specialist (Ayayi)
New York University (Tulsky Toolbox project)	Not distributed yet	Pending approval of contract negotiations from CDMRP Contract Specialist (Ayayi)

*Navy approval status of BADER CRADA:*

*Navy Medical Center Portsmouth (NMCP)*

On June 19, 2013, the PI and Director of the Administrative Core attended a series of meetings with officials at NMCP regarding the status of the omnibus BADER CRADA. The series of meetings at the NMCP were extremely productive. NMCP officials supported the omnibus BADER CRADA concept.

The group met with CDR Greg Nezat who has a central role regarding NMCP research. CDR Nezat was successful in creating awareness at a higher level. As a result of the Nezat meeting, we were invited to a meeting with CAPT James Hancock (Deputy Commander, NMCP), CDR Bill Beckman (Director, Professional Education) and CDR Nezat. During that meeting, we thoroughly reviewed the status of the BADER CRADA (BADER Consortium wide) and the materials indicating Navy (ONR/Ponzio) had rejected the BADER CRADA.

We believe our trip to Portsmouth was effective and that any awareness and momentum generated is championing this forward in a manner that is helpful to the Navy. The CRADA documents were sent to CAPT Ziemke upon our return to UD. We are now in a holding pattern, prepared to assist further upon request.



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**CRADA efforts at NMCS D:**

Based on the efforts at NMCP, Marilyn Wyatt has indicated that she is working with officials at NMCS D to champion the BADER CRADA through their processes. Ms. Wyatt shared the concept that if ONR rejects the BADER CRADA, alternative approval paths may exist. We continue to work with Navy to get the BADER CRADA in place.

We have elevated this issue up the Navy command ladder as far as possible. By meeting with senior members of the Navy command, we intend to create awareness regarding the congressional desire to execute extensive, nation-wide research consortia and the need to implement an omnibus CRADA model system in order to realize congressional (CDMRP) expectations. The road block seems to be Office of Naval Research (ONR). Both NMCP and NMCS D desire to implement the omnibus CRADA, however, we have been unable to communicate with ONR. Considering the efforts to onboard NMCP and NMCS D onto the omnibus BADER CRADA have been unsuccessful, we are currently seeking assistance through our University of Delaware lobbyist to schedule a visit to Capital Hill to request a congressional inquiry.

**Task 8: Evaluation:**

- 8a. Management of internal evaluation process – months 1-60
- 8b. Primary liaison with external evaluation service (AAAS) – months 1-60

BADER Administration has presented to the MTF representatives, External Advisory Committee (EAC) and the Grants Officer Representative (GOR) a plan for having the American Association for the Advancement of Science (AAAS) perform a research evaluation for the BADER Consortium. At this time, the concept is being evaluated by the GOR to determine the extent to which the MTFs are willing to participate in the on-site scientific review process.

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**Clinical Research Core (CRC):**

**Task 1: Facilitate approvals of protocols for the use of human subjects in research through local IRBs and through HRPO**

- 1a. Identify DoD requirements for the protections of Human Subjects in Research (months 1-2).
- 1b. Develop materials for and assist PIs in submitting protocols according to the United States Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) policies and procedures through the ORP for approval (months 2-48).
  - Protocol and Data Management Coordinators have gained access to and utilize the military IRB electronic systems for their assigned location. They are now trained in local IRB guidelines and procedures. Each has been successful at assisting with the preparation of IRB materials and in submitting protocols through their respective IRBs.

- Select CRC staff members have been nominated to site-specific IRB administrative or scientific review committees.
- The on-site staff have performed lab equipment testing for readiness to assess study subjects under the conditions specified in protocols receiving IRB approval.
- Institutional Review Board (IRB) processes and expectations differ between DoD sites (MTFs) and non-DoD sites and among the DoD sites themselves. However, per the BADER Award, all sites participating in a research project must send their IRB records and associated documentation to the Human Research Protection Office (HRPO) at the USAMRMC ORP to obtain final approval before initiating any human subjects research activities. Once HRPO approval has been obtained, BADER Administration sends a letter to the PI providing approval to begin their human subjects research activities. This process has been codified. Depending on the research project, a non-DoD participating site IRB may elect to rely on the DoD site IRB as the IRB of record. At this time, non-DoD sites cannot serve as the IRB of record.
- To help study sites navigate the multi-tiered IRB process, the CRC is developing guidelines outlining the necessary procedures and related forms. The Director of Research met with CDMRP HRPO representatives at Fort Detrick to gain a clear understanding of the IRB process at the CDMRP level.
- Clinical Research Core Protocol and Data Management Coordinators continue to fully participate in and support the approval of protocols through their respective IRBs and through HRPO when required. Specifically, they prepare protocol applications, amendments, and continuing reviews; serve on human subjects protocol administrative review committees; interface with local IRBs to coordinate audits; and maintain secure records of all human subject consent and other PII data forms.
- IAA process: Still in progress is the design of a general guideline intended to facilitate a process of gaining approval for human subjects research activities in a BADER supported multi-center study. The guideline allows one or more participating institutions to cede primary IRB review and regulatory oversight to another participating institution's IRB, who serves as the "central" or Reviewing IRB. The intent is to streamline the documentation work flow process necessary to secure agreements between the University and each of the participating BADER sites. The design process has involved compiling local/institutional procedures and conducting a comparison analysis to identify opportunity to share and adopt processes/procedures across sites in order to streamline and make material preparation, submission, tracking more efficient. At the time of this report, CRC staff is working with the UD IRB compliance officer to finalize the guideline so that it can be embedded into the BADER CRADA and the BADER SOPs.
- The above described guideline will enable the UD IRB to rely in whole or in part on the IRB at another BADER-affiliated institution. This will provide a mechanism for CRC staff on-site at MTFs to engage in human subjects research activities in a supportive role.

**Task 2: Assist in the development, implementation, and monitoring of standard protocol/human subject research activities that will be instituted across MTFs and Clinical Study Sites throughout the BADER Consortium:**

- 2a. Compile detailed descriptions of all of the planned activities/ interventions/ testing sessions etc. in which subjects will participate in each study and identify existing research resources at MTFs and clinical study sites (months 1-3).
- 2b. Identify and hire Consortium Protocol and Data Coordinators Managers (months 1-3).
- 2c. Identify and hire On-site Protocol Managers and Technicians for MTFs and clinical study sites (months 1-6).
- 2d. Identify data storage needs and work with the Scientific Cores to set up policies and procedures relating to coding of research protocols, subjects and associated data across all MTFs and clinical study sites (months 6-12).
- 2e. Train Consortium Protocol and Data Coordinators in modeling protocols in Data Monitoring System (months 6-12).
- 2f. Implement the Protocol and Data Management System (PDMS).

2c: Once all of the Clinical Research Core staff were recruited, they convened for the first time in person on the UD campus for a two-day retreat meeting in March 2013 during which they met with various BADER and University staff. All intended meeting objectives were met and staff indicated that it provided them with a firm grounding in the aims of BADER as well as their roles and responsibilities. Since that meeting, the CRC have met using a video-conference mechanism and will continue to meet on a monthly basis using this format. Weekly teleconference calls continue between each site and the CRC Manager; calls are conducted as needed between the CRC Manager and the MTF point-of-contacts; emails are exchanged on a regular basis.

2c: It became apparent that the CRC Staff has become a strong and united team. Despite geographical distance between most of the staff members, they continue to develop professional and collaborative working relationships. Much of this development has been fostered by the CRC Manager by creating structured opportunities such as monthly research article reviews, which all CRC staff agreed to actively participate in. The CRC Manager also assigned pairs of staff members to take lead responsibility on various tasks, including developing and drafting monthly "BADER Dispatch" informational announcements, generating a comprehensive list and a functional matrix of orthopaedic rehabilitation measurement instruments used with amputees, and taking turns hosting a monthly CRC "all-hands-on-deck" video conference meeting. Some of the staff's relationships have come about more naturally. Even from their remote locations, the team appears to have developed mutual respect and admiration, evidenced by the showing of support and encouragement towards one-another. For example, CRC staff took it upon themselves to join together and show their appreciation for a retiring BADER team member and, more recently, to share their heartfelt support to a team member dealing with hospitalization of a loved one.

2c: The CRC recently experienced three staff changes. Two staff members resigned from their posts to pursue new employment opportunities: a Protocol and Data Management Coordinator at the BAMC Center for the Intrepid (CFI) and a Research Associate at the Navy Medical Center San Diego (NMCSD). MTF representatives at these sites, in coordination with the CRC Manager, will determine if and how these positions will be filled. One CRC staff member has been relocated; the Research Associate at BAMC-CFI was reassigned (in consultation with the MTF representative) to the Spaulding National Running Clinic at Harvard University because it was determined that the Research Associate's skills and knowledge were better suited for the research at Spaulding. This reassignment was collaboratively agreed upon by all parties involved, including Dr. Irene Davis at Spaulding, Dr. Steven Stanhope, Dr. Suzanne Milbourne (CRC Manager), and Dr. Jason Wilken from BAMC-CFI. The Research Associate will now support the BADER Consortium research conducted by Dr. Davis. A new job description to secure a replacement at BAMC-CFI is currently being considered.

2f: **Protocol and Data Management System (PDMS) - data management/storage/reporting functions**

A successful meeting was held (using DCO) on March 29, 2012 across all four MTFs, University of Delaware, Spaulding Rehabilitation Hospital, Mayo Clinic to explore the proposed PDMS system. The meeting was well attended by the MTF representatives including many Information Technology (IT) professionals from the MTFs. MTF representatives approved the concept of the PDMS and gave approval to move forward with a feasibility study.

Meeting outcomes included:

- The development of an ad-hoc team to further study the feasibility of the proposed PDMS (eSphere) product, including contacting NIH officials for eSphere testimonials and recommendations.
- Weekly meetings led by Associate Director, IT-Client Support & Services at UD and the Director of Research to discuss potential roadblocks to implementation. These meetings include MTF IT representatives.
- Open communication and collaboration with IT professionals at UD and the MTFs

Through the due diligence process and conversations with NIH officials, the Consortium Clinical Research Core and IT support staff identified a unique opportunity to partner with a federal agency and deploy a PDMS equivalent to the earlier proposed commercial system yet at far less cost, while still meeting all of the requirements in the ORCCA announcement. MTF representatives supported this change. This partnership is primed to result in a new, highly visible, impactful application of the system in a broad range of orthopaedic rehabilitation studies by Department of Defense and Veterans Administration investigators, as well as other scientists and clinicians. The programmatic strengths of the partners offer synergistic opportunities to accelerate the application of the system for extramural research and allows for funds to be diverted back into the pool of dollars slated for supporting research studies proposed to the Consortium.

Named the Clinical Trials Data Base (CTDB) and designed by the National Institutes of Health, National Institute for Child Health and Human Development (NICHD), the system provides all of the necessary

data collection, management and reporting functions, as well as outcomes and subject recruitment functions. The CTDB is a web-based application that supports secure data management for natural history and clinical trial research studies. It provides key features for protocol study design, data collection, biospecimen tracking, and reporting. Use of the CTDB will reduce redundant data management within the Consortium, reduce data-management training for researchers, enlarge patient registries for future protocols, comply with broad federal-agency data-security requirements, increase ease-of-use leading to improved analysis, and assist with statutory report compliance.

The CTDB and its supporting infrastructure has the capacity for economical sustainability beyond the Consortium funding period. The Consortium's MTF partners vetted and unanimously approved use of the CTDB.

2f: National Institutes of Health (NIH): The Consortium, through the Clinical Research Core, has executed a Collaboration Agreement with the National Institute of Child Health and Human Development (NICHD) for partnering on the use of the NICHD Clinical Trials Data Base (CTDB) as the Consortium PDMS system. This unique partnership is supported by leadership at both NIH and UD and brings substantial opportunities to both parties for future development and now offers the Consortium a secure and dedicated instance of the NIH Clinical Trials Database. Establishment of this partnership saves the Consortium a significant amount in direct costs that would have been spent on the originally proposed PDMS while providing the same (and in some respects enhanced) capabilities. These funds will now be steered toward supporting future research projects.

2f: It was decided that the secure and dedicated instance of the NIH Clinical Trials Database (CTDB) would best live in a natural hosting site. Therefore, the CRC initiated and completed two competitive bidding processes resulting in contract with 1) Carpathia Hosting Inc. for a secure, US-based, managed hosting site. This contract provided hardware, networking and physical security solution required to operate the information system (CTDB) and 2) a contract with TRI-COR Industries, Inc. to guide the Defense Information Assurance Certification and Accreditation Process (DIACAP) compliance and risk management process. The CRC partnered with the Consortium IT staff to coordinate with a risk management security consulting firm to complete the first of five phases of the DIACAP. Primary DIACAP activities completed and/or initiated to date include registering the Consortium and the CTDB system with DoD, assigning information assurance controls, assembling a DIACAP team, reviewing the intent and initiating an information assurance implementation plan. The first of five phases was completed.

2f: However, in year 2 quarter 3, BADER Administration, in discussions with NIH-NICHD, determined that the BADER PDMS should be housed on the NIH servers as a stand-alone instance rather than on a fee-for-service private system such as Carpathia. This decision ensures that the BADER PDMS is an exact mirror image of the NICHD CTDB, which will significantly reduce the on-going maintenance required to address system updates and will streamline any necessary technical assistance. In addition, the BADER PDMS housed on the NIH-NICHD server maintains necessary FISMA certification that was previously acquired. The BADER Risk Management Plan that was designed for use with the Carpathia system consisting of security controls and relevant policies and procedures for the monitoring and use of the PDMS in accordance with both FISMA and DIACAP has been archived.



2f: The BADER version of the NIH supplied CTDB became live this quarter. Modeling of the first two approved BADER projects was tested in the live version. In addition, a comprehensive set of BADER Clinical Trials Data Base (BCTDB) user guides are near complete. A separate instance of the BCTDB was launched and soon thereafter, the NIH implemented a new release.

2f: CRC staff collaborates with the National Institutes of Health National Institute of Child Health and Human Development (NIH-NICHD) to optimize, test and implement a new release of the NICHD Clinical Trials Data Base (CTDB) that is named the BADER Clinical Trials Data Base (BCTDB) and will serve as the BADER Protocol Data and Monitoring System (PDMS). User materials are being revised to accommodate various aspects of the new release. Model work flow processes have been designed using the two initially funded studies that outlines planned research project activities/ interventions/ testing sessions etc. involving human subjects.

2f: A member of the CRC is now stationed on site at the NIH/NICHD and has acquired necessary NIH security clearances to obtain full access to the BCTDB in order to ultimately serve as Master Protocol Coordinator. This individual received training from the NIH staff and is working with them to add all BADER-funded study protocols to the BADER PDMS. Working on site with the NIH staff affords opportunity for this staff member to have direct access to technical assistance from the data base administrators and also to the NIH CTDB reporting system which currently sits behind the NIH firewall.

2f: Efforts are underway to establish a government oversight committee for the BADER PDMS. This committee will be responsible for making recommendations and guiding the implementation of policies and procedures relating to use of the BADER PDMS, such as the naming convention for protocols entered into the BADER PDMS and the use of Common Data Measures throughout the Consortium. Members of the BCC and B3C agree on the establishment of such a committee and are in the process of selecting the representatives who will be invited to serve on the committee. The committee is expected to include representatives from the Scientific Core, BADER-supported investigators and/or BADER Consortium Affiliates.

2f: The identification and implementation of a PDMS across the four MTFs could become an integral part of the EACE mission of providing a "...network of continuous care and study of amputations and extremity injuries...from point of injury thru definitive care and rehabilitation, into lifelong surveillance in order to reduce the disability and optimize the quality of life for Service Members and Veterans." The Deputy Director for Research for EACE has been involved in the feasibility study of the PDMS for the BADER Consortium and we would be supportive to EACE should they seek guidance on implementing the same PDMS into the VA system. The BADER Consortium proposed PDMS (eSphere) would provide the capacity to share data across institutions from MTFs to VA sites and support the EACE mission.

**Task 3: Provide training and oversight to On-site Protocol Managers, Technicians and other relevant personnel in study procedures:**

3a. Develop and provide training to On-site Protocol Managers and oversee the coordination and maintenance of Institutional Review Board and ORP approvals, including initial review and approval processes, continuing renewal processes, amendment, and addendum and termination approvals.

(months 9-60).

3b. Develop and provide training to On-site Protocol Managers, and oversee procedures to recruit subjects, track accrual, track human subjects compliance, schedule tests, and report adverse events to the ORP and local IRBs. (months 9-60)

3c. In conjunction with the Scientific Cores, develop and coordinate training for the Consortium Data Coordinators, On-site Research Directors and Technicians and other relevant personnel in data collection and management and quality control procedures (months 12-60).

3a: All CRC staff have completed relevant CITI human subjects protection training required to meet IRB and ORP approvals. Annual updates are completed as necessary.

3b: All on-site staff completed CITI training relevant to study procedures for conducting research with human subjects. Additionally, two CRC Protocol and Data Management Coordinators passed the qualifying exam to become Certified Clinical Research Coordinators (CCRC®). The CCRC® credential is designated to a clinical research coordinator who has met eligibility requirements, demonstrated proficiency of specific knowledge and job-related skills, and passed the standardized Academy of Clinical Research Professionals Clinical Research Coordinator *Certification* exam.

3b: CRC staff complete any and all required site-specific training related to research regulations and compliance.

3b: Some on-site staff have initiated and organized lab and/or project coordinator-type cross-departmental informational/planning meetings and others have created organizational systems for tracking study documents, procedures and resources.

3b: CRC staff from each MTF participates in a weekly conference call with the Clinical Research Core Manager to discuss issues related to human subjects research generally and specific to their study site research projects. The Protocol and Data Management Coordinators have intermittent communications among themselves as the need arises for technical assistance.

3b: All CRC staff participate in a virtual face-to-face meeting each month to discuss a variety of topics related to the coordination and conduct of research. The sites take turns on a rotating basis for hosting and facilitating the meeting.

3c: Coordinators and Research Associates have engaged in open communication with the Scientific Technical Cores for assistance with individual protocols issues related to data management and quality control procedures.

3c: CRC staff initiated the "BADER Dispatch" of information related to protection of human subjects, IRB processes, federal regulations, etc. The Dispatch, targeted at BADER Affiliates and Investigators, is posted monthly on the BADER website.

**Task 4: Monitor protocol activities and notify Administrative Core of inadequate study procedures, training or subject recruitment that requires input from the BADER Consortium Coordinating Center**

- 4a. Develop tools for reporting progress in of training activities, subject recruitment and testing, data analysis and quality control measures (months 6-24).
- 4b. Track study progress monthly and notify Administrative Core of underperforming sites and suggest solutions to improve performance (months 12-60).
- 4c. Provide input to Administrative Core for quarterly progress reports of clinical research studies (months 4-60).

**Table 3: Key dates for BADER funded research projects**

	<b>2012.1 – Step2Step</b>	<b>2012.2 - RETRAIN</b>	<b>2013.1 – ProLeg Rx</b>	<b>2013.2 – K2Power</b>	<b>2013.3 – Outcomes Toolbox</b>
<b>Proposal submitted</b>	October 2011 (part of original ORCCA submission)	October 2011 (part of original ORCCA submission)	December 16, 2012	December 16, 2012	December 16, 2012
<b>Scientific Review</b>	May 2011	May 2011	December 2012	December 2012	December 2012
<b>GSC approval</b>	April 2012	June 2012	March 18, 2013	March 18, 2013	March 18, 2013
<b>Contract negotiation docs sent to CDMRP</b>	June 2012	July 2011	Aug 5, 2013	Aug 5, 2013	Aug 5, 2013
<b>CDMRP approval</b>	August 2012	August 2012	pending	pending	pending
<b>Omnibus CRADA executed</b>	December 2012	October 2012	Pending VA review	Amendment pending CDMRP administrative review	Pending due to Tulskey relocation to NYU
<b>BADER PI agreement signed</b>	August 2012	October 2012	April 2013	pending	pending



<b>IRB approvals</b>	August 2012	June 2013	pending	pending	pending
<b>HRPO approval</b>	September 2012 (aim 1)  April 12, 2013 (aim 2)	June/July 2013	pending	pending	pending
<b>Subjects recruited</b>	0	0	0	0	0
<b>Presentations</b>	3	1	0	0	0
<b>Publications</b>	3 (pending review)	0	0	0	0

4a: Progress reporting on training, subject recruitment and testing, data analysis and quality control measures will be conducted using the auditing and reporting functions of the BADER protocol and data management system.

4b: To date, no study subjects have been enrolled and therefore, no progress reporting has been conducted. However, HRPO approval has recently been granted and recruitment has begun for the two initial projects.

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### **Task 5: Research Development**

- 5a. Identify gap research areas.
- 5b. Identify and secure sources of external funding.
- 5c. Connect BCAs with potential collaborators.
- 5d. Create research pipeline of tech development to basic research to clinical trials.
- 5e. Support research development at MTFs

5b: Collaboration with METRC: Members of the BADER Consortium were active participants in the development of the ProFIT study proposal to be submitted to CDMRP under the Idea Development Award mechanism. This collaboration is the first between BADER and METRC and we look forward to future collaborations.

5a. At the June 2013 BADER Annual Strategic Planning meeting BADER Administration worked together with the Director of EACE and the MTF representatives to identify gap areas for research. Within the identified gap areas, three focus areas were selected for the BADER Call for Proposals.

5b. We continue to identify relevant Requests For Applications (RFAs) from the NIH DoD and select non-federal agencies and post them on the BADER Consortium website.

5e: TATRC: Dr. Stanhope and Dr. Wilken are members of the TATRC LEGS initiative team.

5e: Other initiatives have been put in place to support research development at MTFs including:

- Subject recruitment initiative
- Travel policy to promote collaborations and communications
- Two MTF researchers are planning to apply to the University of Delaware PhD program in Biomechanics and Movement Sciences and will utilize the free tuition support provided by UD.
- CRC staff are supporting XX projects at the MTFs

#### 5c: BADER Consortium Affiliates

A major eligibility criterion to receiving Consortium support for research projects and Core support is being a BADER Consortium Affiliate (BCA). In the initial proposal phase as well as over the first year, leadership in the Consortium and MTFs identified the first 40 BCAs. The list has expanded to include over 90 BCAs, and continues to grow as we continue to build research teams and partnerships. See Appendix D for full list of BCAs

A BADER Consortium Affiliate is an expert in an area of orthopaedic rehabilitation care, research, technology, or administration who is permitted to engage the BADER Consortium in the identification, planning and execution of impactful orthopaedic rehabilitation scientific studies and investigations using BADER Consortium resources. In addition, BCAs may help to promote orthopaedic rehabilitation research at each Military Treatment Facility by mentoring emerging scientists. BCAs may also assist with sustaining the BADER Consortium by conducting externally funded and BADER Consortium affiliated projects. BCAs will have access to BADER Consortium information and communication resources and are encouraged to engage the BADER Consortium to establish lasting orthopaedic rehabilitation research partnerships.

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Once accepted as an Affiliate the BCA will qualify to:

- participate in the BADER Consortium research project program and qualify to receive BADER Consortium research support;
- receive services provided by the BADER Consortium Scientific Technical Cores;
- access Consortium website secured materials and receive limited distribution program announcements.

5c. The BCA information has been expanded on the BADER website to assist in facilitating collaborations. We are also developing a partnership with the Amputee Coalition that will provide opportunities for a large number of individuals with limb loss to participate in BADER Consortium funded studies.

5e: Dr. Davis, Director of Clinical Research for BADER, and Dr. Stanhope worked closely with CAPT Gregg Ziemke at Naval Medical Center Portsmouth (NMCP) to explore potential research initiatives for the site. NMCP has a strong desire to develop a robust research-intensive culture.

5d: While the BADER Consortium is prohibited from funding technological development projects, it does serve as a model technology translation partner. BADER continues to establish collaborations

with orthopaedic rehabilitation technology groups and external funding sources to support the development of advanced technologies and rapidly translating exciting new technologies into clinical trials and patient care settings. The following are examples of this:

- **BiOM:** The Director of the BADER Consortium was invited to participate in a local (Newark, DE) demonstration of the BiOM Bionic Lower Leg System. BiOM is partnering with the BADER Consortium for a large scale clinical trial of the BiOM product (Linberg, K2 Power Study). This is a remarkable opportunity to bring an interdisciplinary research project to the DoD and VA.
- **Ossur and Otto Bock Health Care:** The Director of the Scientific Cores has been discussing opportunities for partnerships between these two prosthetic and orthotics industry leaders and members of the BADER Consortium. Ossur and Otto Bock provided strong letters of support for the BADER Consortium during the proposal phase and we are excited to potentially engage each of them in large scale clinical trials across the MTFs and VA Centers.
- **Bertec:** Preliminary discussions have taken place with this international industry leader in force measurement technology for biomechanics, in hopes of expanding MTF research capabilities for their instrumented treadmill.
- **Bertec, IAI, C-Motion and BADER** are currently collaborating on a technology development initiative.
- **Simbex:** Through Dr. Davis' research project, this leader in the application of biomechanical feedback systems will provide monitoring equipment. The BADER Consortium is interested in pursuing other opportunities to engage their expertise with more of its research activities.

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**METRC:** Under the leadership of Drs. Darnell and Milutinovich, BADER, METRC and several senior DoD officials met in Ft. Detrick on March 22, 2013 to explore opportunities for the Consortia to work together. This very productive meeting covered key topics including key objectives and overview of each Consortium, strategies for accessing the MTF populations, potential for sharing resources and future collaborations.

**Veteran's Affairs (VA):** Two of the recommendations coming out of the first GSC meeting were centered on getting the VA sites involved as affiliates. The Director of the BADER Consortium has engaged the Director of Research at the VA to determine a path forward on this initiative and determine the appropriate personnel within the VA to develop and execute partnership strategies. Three VA Regional Centers of Excellence (Seattle, Providence and Denver) have been identified by Dr. Stanhope and as potential collaboration sites based on their portfolio of orthopaedic rehabilitation research. Two of those sites (Seattle and Denver) are within the scope of EACE which further strengthens the collaboration of EACE and the BADER Consortium. We were briefed by the VA with regards to plans for clinical trials of the DEKA Arm and have agreed to facilitate upcoming and future clinical trials. Dr. Tim Brindle of the VA attended the BADER Annual Meeting. We have been collaborating with a team at the VA DC office to identify best practices for engaging VA sites in future BADER Consortium activities. This includes

partnering in a “state of the science” meeting. In addition, the Consortium is developing informational materials for distribution across the VA.

The Center for Rehabilitation Sciences Research (CRSR): The BADER Consortium is delighted to report the Consortium Biomechanics Core provided critical support to the CRSR project aimed at establishing common gait analysis data collection capabilities across three of the MTF sites. Dr. Kaufman, Director of Consortium Scientific Cores coordinated the effort.

DARPA: Members of the BADER Consortium continue working on a \$3M DARPA award to develop a process for the rapid manufacture of composite passive dynamic AFOs.

Edgewood Chemical and Biological Center (ECBC): The Consortium has established a CRADA with the DoDs, Advance Design and Manufacturing (ADM) team at ECBC in support of the development and exaction of our Rapid Manufacture of Personalize Rehabilitation Devices (RaMPeRD) initiative.

SAIC: Partnering with SAIC on “Defense Technical Information Center (DTIC) Homeland Defense (HD) Technical Area Tasks (TATs)” with the potential to compete for up to \$900M in task orders. SAIC has been selected as a participant with the ability to apply for funding as TATs are released.

#### **Government Relations:**

UD Day in DC: The BADER Consortium was highlighted in the second annual UD Day in DC. This event highlighted key research programs at the University and was attended by over 300 legislative staff, government program officials and UD Alumni. Senators Coons and Carper and Representative Carney also attended.

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Dr. Stanhope travelled to Capitol Hill to visit the offices of Senators Coons (D-DE) and Carper (D-DE). The briefing meetings resulted in plans for a spring BADER Consortium event on the Hill and a visit by Senator Coons to ECBC in support of the partnership between the BADER Consortium and ADM.

Senate Bills 521 and 522: BADER is working with the UD Director of Federal Relations to express interest to our Congressional delegation in getting the following passed:

S521: Wounded Warrior Research Enhancement Act - Directs the Secretary of Defense (DoD) to award grants to carry out research for the advancement of orthotic and prosthetic clinical care for members of the Armed Forces, veterans, and civilians who have undergone amputation, traumatic brain injury, and other serious physical injury as a result of combat or military experience. Includes under such research the prevention of amputations, orthotic and prosthetic intervention, and orthotics and prosthetic materials and technology research.

S.522: Wounded Warrior Workforce Enhancement Act - Directs the Secretary of Veterans Affairs (VA) to award grants to eligible institutions to: (1) establish a master's or doctoral degree program in orthotics and prosthetics, or (2) expand upon an existing master's degree program in such area.

### Collaborations with industrial partners:

Discussions continue with multiple industry partners to further engage with the BADER Consortium.

Those include:

- C-Motion, Inc. – (Biomechanics Core). Implementation and dissemination of the several power and energy movement analysis techniques across MTF and affiliated sites.
- Intelligent Automation Inc., Body weight support treadmill training and remote movement monitoring.
- Simbex, LLC – Engage the TREAT resources to explore emerging rehabilitation technologies that may be suitable for future clinical research studies through the Consortium. TREAT is part of the National Institutes of Health (NIH) R24 network of rehabilitation research resource centers. TREAT focuses on technology transfer and comparative effectiveness research.
- BiOM Inc.,
  - Clinical study using the BIOM robotic prosthetic ankle joint has been approved to start this October at WRNMMC under the direction of Alison Linberg, DPT.
  - BADER met with representatives of BiOM at the recent Amputee Coalition meeting in Orlando FL. We are currently working with BiOM to organize a briefing of their products and collaborations to BADER.
- Ossur, Inc. Manufacturer of running specific prostheses with the goal of customizing functional characteristics. Supported a BADER Consortium research proposal with the commitment of free prosthetic devices.
- Otto-Bock: Supported a BADER Consortium research proposal with the commitment of free prosthetic devices.
- Bertec, Inc. Implementation of instrumented treadmills for patient assessment and intervention.
- The Opensim project, Development of simulation models for assistive technology.
- Independence Prosthetics and Orthotics, Inc., Regional P&O expertise in support of the DARPA funded project.

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### Problem areas related to Task 5:

- With the recent announcement of COL Rachel Evans retirement, we have concerns about our partnership with EACE which has been remarkably positive and we have realized much better and more open communications with the MTFs. We are delighted to be working with the EACE initiative to be able to drill down on existing research projects to increase the level of transparency.
- BADER affiliates are beginning to seek external funding, but not necessarily linking their efforts to the BADER Consortium. We are aware of at least five pre-proposals that were submitted to the PRORP RFP. Three of these pre-proposals solicited support letters from the BADER Consortium which is strongly encouraged in order to develop the sustainability model. However, at least two proposals were submitted without mention of the Consortium even though the Consortium assisted in the proposal preparation.



*Proposed corrective actions:*

Develop more formal approaches of promoting the Consortium capabilities and resources to facilitate support of the proposals and demonstrate value added by engaging the Consortium. Provide greater outreach to affiliates and MTFs to indicate the research BADER research infrastructures they now rely on must be sustained through future research awards.

**Task 6: Development and Coordination of the Call for Proposals**

A primary function of the BADER Consortium is providing funding for multi-site clinical orthopaedic rehabilitation research studies. An extensive amount of effort has been put forth by MTF representatives, EACE Research Director and Consortium leadership to identify research gap areas and determine focus areas for the BADER Call for Proposals.

Once the focus areas for the Call for Proposals were agreed upon, the BADER Consortium leadership worked together to develop the Call for Proposals document, as well as all of the supporting documents and forms that were needed to support the call. Details for each Call can be found below.

While large, randomized controlled clinical studies are expected to be part of this consortium effort, multi-site cohort comparison effectiveness studies, innovative systems of care studies, translational studies of technological developments and descriptive clinical pathway(s) evidence-based outcome studies are also appropriate. All studies shall be limited to clinical research and clinical trials that aim to change patient care/patient care pathways and result in increased patient functional outcomes. Animal, drug and technology development studies are excluded from consideration.

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Three types of proposal funding models are considered:

- A. Proposals fully supported by BADER Consortium funding and core resources
- B. Proposals supported by a combination of BADER Consortium funding and external funding
- C. Proposals that are fully supported by external funding and request Consortium support to utilize core resources

**FIRST CALL (2012 – Year 1):** In May 2012, a strategic planning meeting was held between the BADER Consortium Leadership, the MTF representatives and the Research Director of the EACE. Following a review of the EACE research priorities that were developed by EACE through collaboration with the MTFs, each MTF representative presented a summary of relevant studies conducted at his/her facility. Discussions then centered around identifying which research gaps best fit the mission of the BADER Consortium, were pivotal to the EACE, and would best interface with the present research areas of the MTFs. To avoid overlap in research topics, the team excluded topic areas that are already being well-addressed with other intramural and extramural military funding. Finally, each participant of the meeting casted his/her vote for the top three focus areas and the following research gap areas were identified:

1. Community re-integration including development and assessment of health and functional outcome measures of ability to return to work/duty

2. Functional outcomes in upper extremity trauma.

3. Return to high performance activities following lower extremity trauma.

The BADER Consortium submitted materials to CDMRP for feedback on the Call for Proposals process and determinations. Feedback was received July 20, 2012 and was incorporated immediately and returned for approval by the GO/GOR. Upon approval, the call was released on September 14, 2012. The timeline for the first Call for Proposals:

Call Announced	September 14, 2012
LOIs due	November 15, 2012
Proposals due	December 16, 2012
Scientific Review:	December 2012
GSC selection:	March 18, 2013
Announcement	April 1, 2013

Pursuant to the initial Call for Proposals, BADER Administration worked with the Chair of the Research Advisory Committee (RAC) to identify appropriate reviewers for the research project proposals. Review materials were sent to the Chair of the RAC who forwarded them onto the review panel. The Research Advisory Committee was assembled based upon the topic areas of the submitted Letters of Intent. Once the proposals were reviewed, the summary statements and the proposals were forwarded to the Government Steering Committee (GSC). The GSC made recommendations for funding of three proposals, with some suggested revisions on their scopes and budgets.

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A summary of the first call for proposals:

Letters of Intent received	12
Total number of research proposals received	11
Proposals received, administratively screened out	4
Proposals forwarded to Research Advisory Committee (RAC)	7
Total dollar amount requested*	\$12,077,361
Proposed numbers of human subjects*	20-500
Number of collaborating sites*	2-7
VA sites identified as collaborators*	5
MTFs identified as clinical sites*	
WRNMMC	5
BAMC	1
NMCSD	2
NMCP	0
BADER Consortium Cores utilized in proposal preparation*	
Biomechanics Core	4
Biostatistics Core	5
Outcomes Measurement Core	5

Note: We received 11 full applications, 7 of which passed the administrative review and were forwarded to the Research Advisory Committee. The remaining 4 proposals were received after the announced deadline of 5 pm EST, December 17, 2012, and were thus removed from the potential funding group for administrative reasons.

**SECOND CALL (2013 – Year 2):** Consensus was reached among the BCC regarding the three focus areas for the second Call for Proposals. The 2012 Call for Proposal materials were revised to reflect the new focus areas and the new deadlines. Approval of the research gap areas was received from the GOR and the Call for Proposals was announced on September 1, 2013.

Proposed timeline for 2013 Call for Proposals:

Call Announced:	August 1, 2013
LOIs due:	October 1, 2013
Proposals due:	November 18, 2013 (revised from original Nov 1 date due to partial government shutdown)
Scientific review:	December 18, 2013 (revised from original Dec 15 date due to partial government shutdown)
GSC selection:	To be determined
Announcement:	April 1, 2014

Research priorities established for the second Call for Proposals:

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1. Determine factors that predict development and successful treatment of musculoskeletal conditions following severe extremity trauma and/or deployment related musculoskeletal injuries.
2. Determine the optimal treatment strategies to minimize impairments, maximize function and performance, and/or achieve optimal quality of life.
3. Develop metrics that effectively quantify changes that result from rehabilitation or provision of novel technologies.

At the time of this report, we have received four Letters of Intent.

For this Call, we offered support to the PIs with the development of their research proposals by making available to them the services of our Administrative, Statistical, Biomechanical and Outcomes cores. BADER also offered these services to those PIs who were not funded during the last Call for Proposals in order to strengthen their proposals that may be submitted for external funding or for BADER funding in this Call.



## Scientific Technical Cores:

### Biomechanics Core (BC): C-Motion, Inc.

#### Task 1: Assessments

##### **1a. Assessments of all MTF equipment, facilities, motion capture technologies, clinical testing processes, and quality assurance policies and procedures (months 1-6).**

This task is completed.

The Biomechanics Core (BC) team conducted site visits at three of the MTFs (note: NMCP does not have a laboratory), gathering information on existing capabilities, feedback on anticipated needs, and a wish list of proposed enhancements to software and hardware systems. The initial visits were intended to introduce the BC, to discuss potential collaboration in person, and to receive initial requests for developments. These visits also provided background on current lab competency with respect to their motion capture systems, force platforms, and treadmills. Table 4 provides a summary of each initial MTF visit.

Table 4: Summary Biomechanics Core visit to MTFs

Location (dates of visit)	Notes on visit
Naval Medical Center San Diego (Oct 19-21, 2011)	Met with Ms. Wyatt to discuss needs of MTF to outline collaboration. Conducted spatial testing of motion capture system and force plate. Based on discussions with NMCS, C-Motion will implement an optimization strategy. Provided Visual 3D training to staff. Will also provide report enhancement per the MTF request.
Walter Reed National Military Medical Center (Oct 2, Nov 7, 2011, May 10, 2012)	Tested and resolved some force plate errors. Significant analysis of data collected to prepare for follow-up visit. On the follow-up visit, the C-Motion group independently tested the motion capture system. The C-Motion group travelled to Vicon headquarters and spent several hours addressing a calibration problem which has now been resolved. At the time of this report, WRNMMC has not availed themselves to the opportunity of Visual 3D training or discussion of the needs of the MTF through the Consortium. C-Motion visited WRNMMC on May 10 to collect data and test optimization routines in an effort to develop a more accurate method for locating force platforms within instrumented treadmills.

San Antonio Military Medical Center/Center for the Intrepid (Oct 26-27, 2011)	Met extensively with Jason Wilken to discuss needs and expectations of the Consortium and the 'wish list' of the MTF regarding the Biomechanics Core. Testing of the motion capture system took place along with training on Visual 3D. A considerable amount of time was spent researching the optimal protocols for the instrumented treadmill and motion capture system.
Naval Medical Center Portsmouth (no visit)	C-Motion did not visit NMCP as they do not have an active biomechanics lab at this time. If a lab is created, the BC would welcome the opportunity to visit at the earliest possible time. It is noted that C-Motion is available to conduct testing at Old Dominion University if their collaborations are still active.

**1b. Assessment of MTF commonalities and collaborative standards and processes (months 1-6).**

This task is completed. Three MTFs (NMCSO, BAMC, and WRNMMC) have had multiple site visits for testing of their motion capture systems and force sensors. At the initial site visits, two of the three MTFs had problems with the calibration of the 3D motion capture volume, and with the parameters that define the location and processing of the force platforms. The problems in the NMCSO laboratory were resolved during the site visit. The problems in the WRNMMC laboratory were resolved on subsequent visits. These three MTFs are now capable of collecting high quality biomechanics data.

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**1c. Evaluation of the MTF CAREN Virtual Reality systems for Visual3D integration and data collection support (months 1-6).**

This task is ongoing. The CEO of Motek (CAREN System) has declared that Motek will not permit integration of their software with Visual3D or any other software developer. The CAREN System has therefore not been quality assurance tested adequately for future multi-site biomechanical studies.

The BC was able to use the CAREN Laboratory at WRNMMC to run the Vicon Nexus software in conjunction with their Visual3D server. The BC tested the CAREN Laboratory instrumented treadmill to confirm that the accuracy of the treadmill output data was sufficient to supply the event detection required for the biofeedback walking protocol. The BC also tested whether the ground reaction force data from the treadmill had sufficient accuracy to detect heel-strike transients during running. As of the end of the quarter (June 30, 2013), a determination has not been made as to whether the CAREN treadmill testing can be used in running biofeedback studies. Evaluation is ongoing.

**1d. Evaluation of motion capture protocols, marker sets, processes, and data management (months 1-6).**

This task is completed. Each of the three biomechanics-intensive MTFs has established its own data collection protocol for motion capture. MTF representatives state that they are satisfied with their individual protocols and have declared that they are not planning to change to be consistent with the

other laboratories. In addition, each laboratory has different coordinate system definitions and different marker protocols. This inconsistency does not pose an insurmountable problem because the local coordinate systems are consistent anatomically. It does mean, however, that close attention and extra effort must be taken when comparing data collected at different laboratories.

***1e. Dissemination of collaboratively developed protocol standards to MTFs (months 6-12).***

A standard protocol has been developed and is ready for implementation across MTFs.

C-Motion has created a document for establishing the data collection protocols and a laboratory checklist for the CRSR study. This document will be shared with the sites as we refine the standard procedures for the laboratories. The expectation is that these protocols will be used as the basis for the BC recommendations. A preliminary version of the document will be shared with the MTFs early in the next quarter.

One of the important issues of standardizing the experimental protocols is to agree on precise definitions (and names) of the palpable bony landmarks used to define the biomechanical models. The guidelines are currently provided on the C-Motion website, but a very specific set of guidelines will be adapted specifically for the MTFs.

**Task 2: Standards:**

***2a. Develop common data management pipelines, scripts, and motion analysis techniques across all MTF and clinical research labs utilizing Visual3D (months 7-12).***

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***2b. Support for “aggressive rehabilitation” protocol adaptations (months 7-60).***

***2c. Evaluate the protocols for pooling and sharing data across institutions (months 7-60).***

The Biomechanics Core (BC) has been supporting the MTFs during the development of their individual data analysis pipelines. The BC has created (and shared) a model procedure document for establishing the data collection protocols and a laboratory checklist for the CRSR study titled “Comparison of 3-D Gait Analysis Data Across Department of Defense Sites” (Appendix A), but the MTFs have decided to maintain using their current individual protocols and processing methods. A decision to consolidate across the sites may still happen at a later time.

The Biomechanics Core continues to work on a customized database and standardization data analysis procedures for the MTFs. The data set will be a formal document for describing the marker sets coordinate systems and model definitions that BADER collaborators can review and use for consistency with the MTFs. The data were generated from multiple marker protocols simultaneously for comparisons across the different protocols used by the MTFs. The Core Director believes that all marker sets used by the MTFs and their collaborators can now be accommodated in a standardized manner.

The Biomechanics Core started collecting control data for gait as part of an effort to develop a data set that will be a formal document for describing the marker sets coordinate systems and model definitions

that BADER collaborators can review and use for consistency and comparisons across the different protocols used by the MTFs. The marker set was further refined through the first 30 subjects and has since been finalized and experimental protocol established. All marker sets used by the MTFs and their collaborators can now be accommodated.

Considerable effort was put into building a stand-alone application for biofeedback to allow more flexibility in adapting custom biofeedback. On Oct 26, 2012, a representative from C-Motion, Inc. spent the day at WRNMMC testing the new biofeedback applications. The applications were tested in both WRNMMC motion analysis laboratory and in the WRNMMC CAREN laboratory.

The MTFs are now capable of pooling and sharing their data across institutions. Each MTF is using Visual3D's cmo library to store data. This library comprises a hierarchically indexed set of files that can be easily accumulated in a single large library without any translation or manipulation. In other words, a library of files from one institution can be merged with a library of files from another institution and the total library can then be re-indexed automatically making it accessible to all partners.

Data Sharing: A big challenge faced by the MTFs in conducting multi-center trials is to facilitate the sharing of experimental data between the MTFs and collaborators. The Biomechanics Core (BC) has explored options for sharing control data sets, from which the patient data can be compared. A critical part of using large control data bases, and potentially patient databases, is the development of statistical algorithms for identifying acceptable data, and for classifying patients. The BC has initiated discussions related to collaboration on the collection and analysis of control data that will be the basis for quality assurance tests of the laboratories (e.g. is data collection of a control subject in a specific laboratory actually representative of a control subject). Within the BADER Consortium's statement of work this involves the storage of data in a library of hierarchically indexed files that can be easily accumulated in a single large library without any translation or manipulation. In other words, a library of files from one institution can be merged with a library of files from another institution and the total library can then be re-indexed automatically making it accessible to all partners. Visual3D has an indexed format that satisfies these goals, used by the three MTFs already, and this will be the framework for new developments linking this data library with patient information. Since the beginning of the contract award C-Motion has embarked on an entirely new way of dealing with the pooling of data, which in a large measure relies on developing new algorithms for Quality Assurance and new algorithms for assessing data files. The intent is to work closely with the MTFs and their collaborators to ensure that the development direction will satisfy their needs, but funding for this ambitious project falls outside of the BC Statement of Work for the BADER Consortium funding and C-Motion has identified external collaborators and are seeking external funding. The BC has based preliminary work on data that was collected through an externally (non-BADER) funded project ("*Statistical Models for Establishing a Control Data set for Biomechanical Gait Analysis*" Deluzio, Selbie).

The MTFs have decided that new database management was a low priority item because at this time they are satisfied with their current strategies. C-Motion will continue to work in this area through external funding.

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Problem areas related to Task 2:

- The Biomechanics Core is concerned about the challenges of data sharing.

Discussions will soon begin to explore the hurdles that will be involved. The upcoming cross-MTF study on marker placement repeatability and reliability will be the starting point for data sharing because this project has approval across the sites for sharing. C-Motion has a draft document for common laboratory procedures that will be shared with the laboratories early in the second quarter that should mandate essential aspects of the protocol that are required for comparing the data across sites.

The BC has made considerable progress in the development of the hierarchically indexed data files. This development has been more challenging than anticipated, and is the principal cause of the delay in the projected release of Version 5. C-Motion has successfully implemented the new strategy, but considerable testing is still required. The BC made modest progress towards a subject management strategy which links subjects with the hierarchical data files, but which does not link the data files with the subjects.

In anticipation that data sharing will jump to the forefront during the next few years, the BC is exploring options for sharing control data sets, from which the patient data can be compared. Queen's University and Simon Fraser University have agreed to collect data that will be made public through C-Motion. The Biomechanics Laboratory at West Point agreed in principle to collect experimental data for a control data base. All laboratories agreed to follow the guidelines of the BADER Consortium for the experimental protocols.

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**Task 3: Certifications:**

- 3a. Identify DoD processes for the implementation of initial motion analysis Certification procedures (months 7-12).
- 3b. Identify DoD processes for the implementation of additional Certification procedures (months 12-18).
- 3c. Develop Certification procedures and criteria (months 12-24).
- 3d. Initiate the establishment of Certification courses (months 12-24).
- 3e. Develop Certification courses for dissemination and implementation of the criteria (months 24-30).

The MTFs have declared that they are not interested in implementing a certification program. Instead they elected to use the Biomechanics Core to obtaining Visual3D training for their staff as a better use of resources. Training has been provided to NMCSO, WRNMMC and CFI by C-Motion staff between Oct 2011 and April 2013.

The Biomechanics Core recommends that this task be modified to focus on customized training for the MTFs, rather than certification programs. As the number of BADER Affiliated projects increases, we will revisit the need for certification programs.



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**Task 4: Support and Collaboration:**

- 4a. Collaborate with the MTF sites to implement data collection protocols for proposed experiments (months 12-60).
- 4b. Collaborate with BADER projects to implement data collection protocols consistent with MTF guidelines (months 12-60).
- 4c. Implement biomechanical model templates for the MTF and BADER projects (months 12-60).
- 4d. Implement Visual3D processing pipelines for each project (months 12-60).
- 4e. Implement Visual3D reporting templates for each project (months 12-60).
- 4f. Implement process and protocol management standards across MTF sites for new data analysis routines (months 25-60).
- 4g. implement written standards (checklists) for data collection protocols (months 25-60).

The BC has assisted NMCS D and WRNMMC with their existing Visual 3D pipelines and templates for the analysis of biomechanical data on a case by case basis, but the substantive work done on Task 4 has been new software development for one of the BADER affiliated projects.

Spent time with CFI getting the RealTime streaming functioning properly for a non-BADER project.

Marilynn Wyatt (NMCS D) expressed interest in developing more elaborate calculations of the “Work and Energy” of gait. In response, C-Motion has initiated collaboration with Simon Fraser University to implement new metrics of gait efficiency. C-Motion believes that this could be an especially important metric for the gait retraining protocol and possibly for the design of orthotics. It was not part of the original statement of work, but the desired analytical functionality that has come to the fore front because of the initial site visit and C-Motion would like to add the the scope of work.

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In a BADER-related study, a control data set (20 subjects) and analysis collected will be submitted for publication to F1000 Research. This published data set will be a formal document for describing the marker sets, coordinate systems, and model definitions that BADER collaborators can review and consider using for consistency with the MTFs. The data were collected with multiple marker protocols simultaneously for comparisons across the different protocols used by the MTFs.

Implemented a biofeedback client for CFI and NMCS D to report walking speed. The biofeedback applications are being refined based on further testing by the MTFs.

MTFs are considering uniformly implementing a novel (Unified Deformable Power Segment) method developed at the University of Delaware for measuring combined ankle and foot biomechanics.

Staff from WRNMMC received training at C-Motion’s offices in Germantown Maryland. This was extensive Visual3D training that included both introductory and advanced training in Visual3D.

A BC representative visited the NMCS D laboratory to conduct Visual3D training. There are several follow-up discussions with NMCS D to elaborate their Visual3D pipelines and reporting. C-Motion has worked closely with NMCS D on their data sharing project because it required several minor tweaks and bug fixes to Visual3D to meet their needs.

The Biomechanics Core provided essential support for the execution of the multi-site CRSR project geared to compare human movement data across MTF sites. C-Motion was made aware that all three

MTFs satisfied the expected criteria for the CRSR gait assessment/standardization quality assurance tests conducted during the first quarter, but to date have not been presented with the actual results or criteria. The BADER Consortium was happy to support this CRSR study.

The Biomechanics Core supported the development of four Consortium project proposals, but only two of these groups actually requested a letter of support for their proposals.

The Biomechanics Core has assisted NMCS and WRNMMC with their existing pipelines and templates on a case by case basis, but the substantive work done on Task 4 has been new software development for BADER project 2012.2.

**Support of BADER project 2012.2 “Returning to High-Level Performance: Walk to Run Training with Real-time Kinetic Feedback” Protocol:**

- In response the current BADER project on the use of biofeedback for gait and running retraining, the Biomechanics Core expended considerable effort into building a stand-alone biofeedback application framework. These applications provided WRNMMC and Spaulding National Running Center with the custom biofeedback software needed for this project.
- The Core has managed to increase performance of the biofeedback applications and has implemented a user interface that satisfies the requirements in terms of latency of feedback and user interface. They were challenged by the inherent noise in the instrumented treadmill data, and are still working towards more robust algorithms for recognizing gait events in real time. A representative from C-Motion was invited by AMTI (manufacturer of the Spaulding Treadmill) to spend the day in their test facility working with their engineers and getting dedicated time on the treadmill for testing.
- During the period of November 21, 2012 to the end of the quarter ending on June 30, 2013, the Biomechanics Core managed to increase performance of the biofeedback application while implementing a custom user interface that satisfies project requirements.
- On November 21, 2012 the BC received preliminary specifications BADER project 2012.2. The BC has finished implementing these requirements and has delivered the software to WRNMMC and Spaulding.
- BC representatives have visited both WRNMMC and Spaulding to discuss modifications and feature enhancements of the biofeedback software.
- The Biomechanics Core was challenged by the inherent noise in the instrumented treadmill data, and in the process have developed more robust algorithms for recognizing gait events in real time. In addition working with a new Vicon (Software Developers Kit (SDK)) we were able to deliver the kinetic biofeedback at a higher analog rate enabling the heel-strike transients to be clearly visible in runners with a rear-foot pattern.

- In response to the anticipated needs of BADER project 2012.2, C-Motion submitted a National Institutes of Health SBIR project proposal titled “Development of a Low Cost, Real-time Biofeedback Gait Retraining System”. The Phase-I proposal was funded. This SBIR proposed to develop a cost-effective system that would make gait retraining affordable at the level of a VA outpatient clinic or at private physical therapy clinics throughout the country. This would enable the therapy to be available to all wounded warriors regardless of their location, and would not require an expensive research laboratory, nor expert staff.

**International Partnerships and potential future research collaborations:** C-Motion visited Headley Court (British MTF) and Birmingham University to discuss potential collaborative projects. The Headley Court staff has agreed to use the same protocols that are recommended for the MTFs, and have expressed interest in a common workshop to discuss overlapping protocols and projects. The BC has approached the West Point Military Academy, the Canadian Military Treatment facilities and the Canadian Institute for Military and Veteran Health Research, Headley Court (the British MTF), and the Czech Republic Army Research Institute about possible collaboration on data sharing protocols. The BC anticipates that data sharing will take place, so that we can maximize collaborations across numerous entities. All of these institutions have established an institutional desire to be affiliates of the BADER Consortium.

C-Motion has initiated collaboration with Queen’s University, Canada and Intelligent Automation Incorporated (Rockville, MD) based on the premise that interaction of the impaired, intact, or prosthetic hand(s) with the environment can be explored experimentally using a robot capable of simulating the dynamics of objects and surfaces.

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Enhancements have been made to the C-Motion website to provide easier access for MTFs to submit requests, ask for clarification and make recommendations. This enhancement is exclusive to BADER Consortium Affiliates.

A BC representative visited the Motion Lab of Dr. Steven Stanhope at the University of Delaware. Mr. Kepple spent time with engineer Alex Razzook working with the CalTester+ software on the Delaware lab’s new Bertec instrumented treadmill to design new treadmill location scheme. Mr. Razzook received an introduction to the Caltester+ software and will pass on data to the C-Motion office in Germantown for processing once the new UD lab is operational.

**Task 5: Custom Database Development:**

- 5a. Custom database development for specific MTF interactions with Visual3D to facilitate concurrent protocols in use by multiple MTFs (months 13-60).
- 5b. Implement a clinical interface to the database software for clinicians within a specified clinical framework (months 13-60).

The Biomechanics Core has developed a customized database and standardization data analysis procedures for the MTFs. The data set is a formal document for describing the marker sets coordinate systems and model definitions that BADER collaborators can review and use for consistency with the MTFs. The data were generated from multiple marker protocols simultaneously for comparisons across



the different protocols used by the MTFs. The Core Director believes that all marker sets used by the MTFs and their collaborators can now be accommodated in a standardized manner.

However, at this time, the MTF's have not expressed interest in the implementation of a custom database.

**Task 6: Visual3D Enhancements for MTFs:**

- 6a. Integration of existing MTF data collection equipment into Visual3D (months 13-60).
- 6b. Perform experimental tests to estimate the effective latencies of the real-time motion capture systems, including the CAREN system (months 13-60).
- 6c. Test, or collaborate with the appropriate manufacturer, to test all force sensing equipment used in the MTFs (months 13-60).

**Visual3D Version 5:** Improvements to the functionality of Visual3D requested by the MTFs were slated for the Version 5 release of Visual3D. Dr. Selbie visited CFI to present the status of the Visual3D changes and to collect requests for additional changes to Visual3D. C-Motion released a beta version of Visual3D that we believe satisfied those requests. Visual3D Version 5 Beta was released in 2012, but very quickly discovered flaws that needed to be addressed prior to release to the MTFs. These changes were finalized at the end of 2012 and the BC delivered software to the MTFs in early 2013. The Version 5 release is critical to moving forward with new functionality for the MTFs.

Visual3D Version 5 is the framework for the UD Power analysis requested by NMCS D. The Journal of Biomechanics article describing the UD Power analysis was accepted for publication, which meant that C-Motion, Inc could implement the analysis. Version 5 is the framework for mimicking the legacy NMCS D gait report with Visual3D. This, too, will be implemented in the Version.

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On the basis of the first site visits, the MTFs requested that C-Motion develop an optimization algorithm for determining experimentally the position and orientation (pose) of each force platform in the motion capture volume. The initial approach to the development of the algorithm was to incorporate the algorithms into the Visual3D Version 5.0 development source code. Delays in the expected release of Version 5 caused C-Motion to reconsider this decision. In order to deliver this functionality to users sooner, a new stand-alone program for this optimization was implemented and was released to the MTFs for testing. The initial implementation of the code will rely on the MTFs to enter the computed pose estimation manually, but a subsequent release will modify the system files for Vicon Nexus and for Motion Analysis Cortex directly.

**CalTester+ – CalTester & Force Platform Locator:** Based on testing conducted at WRNMMC it became clear that a more accurate method for locating force platforms within instrumented treadmills and stairs was needed before any BADER Consortium human subject testing should begin. This need was corroborated by the other MTFs. To move toward a solution, prototype software (CalTester+) was released for testing at WRNMMC and results were promising. The ability of CalTester+ to improve the ground reaction force data, and the degrees of errors associated with manually guessing the location of the platforms by our several test sites has resulted in the conclusion that all affiliated laboratories collaborating with the MTFs should have CalTester+. C-Motion delivered requested software to

NMCSD and BAMC/CFI to be able to use our specialized CalTester methodology as an experimental device to load the platform in a series of systematic trials. The software was further refined and CalTester+ was tested at several more institutions, which resulted in many more feature enhancements.

Modifications have been completed to correct quirky behavior in Visual3D, including scaling of interactive graphs, and registry settings that aren't preserved. These minor issues were resolved for the Version 5 release of Visual3D.

Provided enhancements to existing commands, including the use of Event Sequence parameters in more commands.

A request has been made to provide enhancements to reporting options. These are more challenging and C-Motion is looking into the feasibility to provide in reasonable time.

Considerable effort was invested in the enhancement of the metrics processing to allow specification of a nested hierarchy of ranges of data; in other words to selectively identify or exclude ranges of data from the statistical analyses of gait metrics.

A formal request was received from San Diego for the implementation of the UD segment power analysis technique in Visual3D. The first step was to modify the original Visual3D pipeline, created at the University of Delaware, so that it would provide a more general solution applicable at most laboratories. The modified script was sent out to two laboratories studying amputee gait who agreed to serve as Beta testers for the script. The implementation of this pipeline as a single Visual3D command is underway and will be guided in part by Kota Takahashi (the scripts original author) and in part by the feedback from the University of Delaware and the Beta tests sites. Given the formal request from San Diego for the implementation of the UD Power analysis, we would like to have this task added specifically to the statement of work.

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***6a. Integration of existing MTF data collection equipment into Visual3D (months 13-60).***

The Biomechanics Core is prepared to integrate existing MTF equipment. At this time, there have been no requests to implement new sensors into Visual3D.

The BC has worked extensively with both manufacturers (Vicon and Motion Analysis Corporation) of the 3D motion capture systems at the MTFs to provide us with license dongles and access to all software needed by the MTFs. This allows C-Motion to proactively test the data capture software before the MTFs receive a new release. The post-processing and real time stream of the pending release of Vicon Nexus has already been successfully tested.

***6b. Perform experimental tests to estimate the effective latencies of the real-time motion capture systems, including the CAREN system (months 13-60).***

We have been focused on the development of the biofeedback application. The gait re-training application is not sensitive to the real-time latency, so this has not been a focus of our efforts. When we are presented with an application that is time sensitive, we will tackle this task.

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**6c. Test, or collaborate with the appropriate manufacturer, to test all force sensing equipment used in the MTFs (months 13-60).**

The BC has worked with AMTI and Bertec who are the manufacturers of the force platforms and instrumented treadmills used by the MTFs. AMTI invited Sandy Whittlesey to their manufacturing facility in Watertown MA for testing and consultation with their engineers. Visual3D and the Biofeedback applications are integrated with the data from the two manufacturers.

Unlike the force platforms in the MTFs, the instrumented treadmills can be repositioned and reoriented relative to the laboratory. Once the optimal pose for the instrumented treadmills is estimated, the MTFs have requested that a process is established for automatically estimating the pose of the treadmills using the results of the optimization relative to motion capture markers placed on the treadmill. This functionality is expected to be delivered in the third quarter.

Problem areas related to Task 6:

- Potential limitations in current software in multi-center trials.

Visual3D has been developed as a research tool, so there are some limitations for multi-center clinical trials. One of these limitations is related to the flexibility that is so beneficial to research because it allows modeling and analysis customized to special experimental protocols. Members of a multi-center clinical trial must therefore be careful that templates and pipelines remain consistent across participating sites. C-Motion has been proactive in tackling a solution to this challenge. Our proposed solution, which will be initiated during the third quarter, is to create a “wrapper” around Visual3D in the form of a relational database that manages the subject data, templates and analyses. In other words, the flexibility of Visual3D can be used to establish custom protocols, but when a multi-center protocol is formalized, this flexibility disappears for that protocol.

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### **Rehabilitation Outcomes Measurement (ROM) Core: New York University (NYU)**

Dr. Tulskey has relocated to NYU from the University of Michigan. The majority of work during this quarter was revising budgets and beginning the process of transferring responsibility for the Rehabilitation Outcomes Core to New York University (NYU). It is hoped that the Core will be fully established at NYU by November 15, 2013.

Over the course of the first two years, the Rehabilitation Outcomes Core has established a good working relationship with investigators at all 4 MTFs. We have performed site visits and met with all investigators at all 4 BADER affiliated MTFs to learn about their research interests, develop strategies for assisting their research programs, and developing collaborative working relationships with investigators at each MTF.

As signs of our success, in collaboration with 3 MTFs, we successfully competed for a BADER funded research study. We have also been working with the NMCSD to set up a pilot study to obtain patient feedback at NMCSD and CFI about quality of life issues and patient reported outcomes.

The ROM provided significant support for research teams on the 2012 call for proposals.

Established collaborations with the VA and NIDRR on the BADER funded Outcomes Toolbox research project.

**Task 1: Establish outcomes library and training libraries, develop infrastructure for working with investigators.**

During the three visits to MTF sites, the ROM Core gathered information on the outcomes measures used at each site, and identified site-specific and more general Consortium-wide needs in terms of outcomes measures.

The ROM Core held a meeting with Suzanne Milbourne (UD), Steven Stanhope (UD), and Dick Sacher (UD) regarding the protocol and data management system that is being set up and tried to coordinate efforts with Dr. Linda Resnik (from VA) and Dr. Tamara Bushnik from NYU who are engaged in parallel processes.

The ROM Core has established a linkage with other investigators who are conducting work in parallel to BADER Consortium. Researchers at New York University are building a data registry to follow individuals who have had lower extremity amputation over time. The VA has a committee that is developing a set of measures to be tracked over time. Dr. Tulskey initiated a meeting with key BADER leadership, Dr. Resnik (from VA) and Dr. Bushnik from NYU to help consolidate efforts. A workgroup was formed.

More problematic is the development of a dissemination and utilization strategy. We need to identify a mechanism to provide BADER affiliates open access to the outcomes library. The Rehabilitation Measures Database website (<http://www.rehabmeasures.org/default.aspx>) could serve as one potential model for what we could build (funding permitting) as part of the BADER consortium. Alternatively, our work could be integrated with the Rehabilitation Outcomes Measurement website to save costs and reach a larger rehabilitation audience.

***1a. Submit relevant IRB related documents as necessary.***

All IRB documents have been prepared. We have secured IRB approval at the University of Michigan and NMCSO. We are now submitting documents to New York University and to USAMRMC Human Research Protection Office and our current plan is to submit to BAMC (CFI).

***1b. Conduct literature reviews to identify relevant outcomes measurement tools related to orthopedic injuries.***

The ROM Core has conducted an extensive systematic literature review to identify outcomes measurement tools that have been used in orthopedic/amputation research. The ROM team has developed a method for reviewing the instruments. A systematic review of each identified scale has been conducted, summarizing the relevant research on the psychometric properties and construct validity. To date, Dr. Tulskey's team has drafted reviews of 28 (out of 45) unique scales of physical functioning. The reviews need to be peer reviewed and finalized. The content of the reviews should be

finalized over the next two quarters. Dr. Tulskey will meet with Dr. Stanhope in Delaware in November 2013 to discuss future plans.

Conducted a broad literature review of health related quality of life and functional outcomes measures relevant to BADER Consortium studies. Conducted a focused review of the research on high-level mobility outcomes measures to develop “common data elements” to be used across the BADER Consortium. The ROM Core is considering adding variables from the PROMIS and the CHAMP as part of these core variables.

***1c. Build measurement library for utilization of relevant outcomes measures for research studies.***

Related to 1b, literature searches and reviews have facilitated establishment of a measurement library for BADER-relevant outcomes measures. The ROM Core has constructed a large, searchable measurement library (Microsoft Excel format) of patient reported, performance-based, and examiner-rated outcomes.

The measurement library currently consists of 28 measures of the physical functioning that have established use in orthopedic/amputation research. Each measure has notes on purpose, administration, availability, and evidence as to the quality of the measure in orthopedic populations.

Electronic and hard-copies of freely-available instruments have been retrieved and filed to aid accessibility of the measures to BADER Consortium researchers.

Created an EndNote file that contains 169 pdf versions of source articles and articles that describe quality indicators (reliability, validity, sensitivity) for recommended measures. This file is updated on a regular basis. The end goal is to develop a measurement library that is accessible to all MTFs through the BADER website. Have received feedback from the BADER Consortium Coordinating Committee on the format and plan for the measurement-based website. The ROM Core has contacted Linda Resnik, PhD. who has been conducting a review of measurement tools for the VA and will attempt to integrate efforts with Dr. Resnik. The ROM Core has developed a methodology from which to conduct the structured reviews.

Developed a review format for reports that will optimize both the usability of this resource and standardize the review process.

Once the reviews and training materials are finalized, Dr. Tulskey will seek input from the BADER Consortium Affiliates to provide a peer review of our work.

***1d. Provide workshops, web-ex presentations, and seminars to train BADER personnel about Patient Reported Outcome (PRO) measures.***

This deliverable concerned the development of training material on Patient Reported Outcomes assessment. During site visits, the Core gave in person presentations to help train BADER personnel about PRO measures and also provided webex training to the Biomechanics Core, as Dr. Selbie



expressed interest in learning more about outcomes measurement tools. Finally, the core has completed a draft of a “stock” patient reported outcomes assessment Powerpoint/WebEx training session to be used with any MTF personnel who will be utilizing PRO measures in upcoming studies.

***1e and f. Prepare training materials for data collection of patient reported outcomes. Prepare measurement platform for BADER proposals (develop Assessment Center or alternative method for data capture).***

In addition to the Powerpoint/WebEx training mentioned in 1d above, a detailed training manual has been developed for any BADER affiliated researcher who wants to utilize PROMIS measurement scales and/or the PROMIS Assessment Center platform. These training materials can be used by BADER affiliated researchers to facilitate PRO assessment in their studies, to train data collectors, and to assist researchers in developing study-specific manuals of procedures. Training topics include the development of an Assessment Center managed study, however the ROM core is available as a resource to all MTFs to prepare Assessment Center (or similar) study administration platforms. These materials will soon be accessible on the BADER website.

**Task 2: Evaluate relevant outcomes measurement instruments and ensure relevance for use in BADER studies. Ensure that floor and ceiling is appropriate for the population. Develop new item content as appropriate.**

- 2a. Develop focus group guides to identify measurement issues.
- 2b. Prepare and execute focus group meetings at collaborating DoD sites (months 2-3)
- 2c. Transcribe focus group guides and prepare NVivo (qualitative software) coding guides (months 4-6)
- 2d. Code and reconcile focus group data (months 7-9)
- 2e. Develop new item content to increase measurement sensitivity/specificity of orthopedic injuries (months 10-12).

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Continue work with Suzanne Milbourne, Dick Sacher, and Scott Selbie to utilize NIH Toolbox within BADER partner sites if necessary. The ROM Core has worked on the Toolbox development and received specialized training in teaching standard administration procedures to new examiners.

Overall progress to date on Task 2: Focus group guides have been developed. However, Task 2 is dependent upon IRB/HRPO approval to conduct focus groups at MTF sites. IRB approval has been obtained at NMCS and University of Michigan. Given Dr. Tulskey and Ms. Kisala’s move to NYU, the team will have to submit for IRB Review at NYU. The ROM Core will work with BAMC/CFI for similar approval as well as with USAMRMC Human Research Protection Office. Upon all IRB and HRPO approvals, the ROM Core is will prepare to collect data at all MTFs to develop common data elements and develop targeted measures for use as BADER outcome variables.

David Victorson from Medical Social Sciences of Northwestern University will serve as the moderator of the focus group. Dr. Victorson has extensive experience running focus groups with a variety of patient populations. He has led several groups to develop patient reported outcomes. Finally, he has



collaborated with Dr. Tulskey on several studies related to patient reported outcomes in individuals with disabilities and worked extensively on the Neuro-QOL test development.

The ROM Core consulted with researchers at University of Washington (Hafner, Amtmann), who are developing patient reported outcomes measures for individuals with lower extremity amputation, to investigate possible ways to augment and utilize their technologies in BADER studies. We will determine if this work is relevant for the MTFs' clinical care and research efforts, identify any gaps that exist and whether the research should be modified in any way.

Problem areas related to Task 2:

- 1) IRB approval is a pre-requisite to conducting this scope of work. Our timeline has been delayed. Given the need to obtain IRB approval at NYU, there will be some additional delays before this can start.
- 2) There is some recent, unpublished, work that is currently being conducted at the University of Washington to develop a new PRO measurement tool for individuals with lower extremity amputation. Ideally, we should avoid any duplication of effort and, if feasible, might change our focus slightly to avoid such duplication.

### **Task 3: Consult and review study proposals for the BADER Consortium**

#### **3a. Submit relevant IRB related documents as necessary.**

An IRB submission is currently pending to initiate a new study at NMCSO and CFI. This is for the pilot work on PRO measures under SOW Task 2. Dr. Tulskey will be working with collaborators on the recently funded "assessment toolbox" project.

#### **3b. Work directly with prospective PIs of BADER projects. Provide consultation on outcomes measurement design issues and integration into proposals and research methodology.**

The Rehabilitation Outcomes Core is very well integrated with the MTFs, continues to provide assistance as needed and develop new collaborative projects. In our first year of funding, we conducted site visits at 3 MTFs (WRNMMC, BAMC/CFI, and NMCSO) and conducted a meeting/site visit at NMCP in Spring, 2013.

The Outcomes Measurements Core is collaborating with the MTFs to accomplish the following goals:

- Compile a list of outcome measures used for O&P studies.
- Perform a formal review of the outcomes measures:
  - Outcome measures in Lower Extremity Prosthetics
  - Outcome measures in Upper Extremity Prosthetics
  - Outcomes measure in Orthotics
- Develop detailed procedures for appropriate collection of outcome measures.

- Develop outcomes measurement tools that could be coordinated as standardized variables across the MTFs. This goal is in response to contact and the request of Jason Wilken (CFI), Marilyn Wyatt (NMCSO), and Erik Wolf (WRNMMC). Dr. Tulsy served as PI for a submission to the 2012 Call for Proposals and was awarded a \$2M research project titled : “Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma”
- Continue to provide letters of support and services to potential BADER Investigators. Contacted by five potential investigators and provided a letter of support for four BADER Consortium proposals in the 2012 Call for Proposals. Two potential investigators requested services from the BADER Rehabilitation Outcomes Core and included potential funding within the budget. Had preliminary discussions and provided letters of support for 3 additional BADER proposals for the collaborative consortium call for proposals. Dr. Tulsy has provided assistance to prospective applicants for the BADER submission and discussed protocol and his core’s availability for consultation and collaboration with 4 prospective investigators during the previous competition. Dr. Tulsy has consulted with two investigators about their proposals being submitted in this current funding cycle (Fall, 2013).
- Continue to provide support to current BADER Investigators. Had discussions with Gregg Ziemke at NMCP to see if there is anything the Core can do to further their research plans. The ROM Core has had conference calls with CAPT Ziemke’s research partners at New York University. Dr. Tulsy is assisting with the design and implementation of Alison Linberg’s BADER proposal. He collaborated on the submission. Continue to discuss possible collaborations with Jason Wilken to see if any other project ideas should be pursued at this time.
- Continue to build collaborative team with the VA and NIDRR. Dr. Tulsy submitted a proposal (“Assessment Toolbox”) in the last BADER grant cycle based upon the request of the investigators of three MTFs. As part of the effort, he developed collaborations with Linda Resnik of Providence VA to ensure that leading VA researchers were participating in a meaningful way on the BADER consortium. Additionally, Tamara Bushnik who is leading a NIDRR funded grant examining outcomes of individuals with amputations was also included as part of the collaborative team.
- Work continues on developing the IRB protocol for the new “Assessment Toolbox” BADER grant awarded to Dr. Tulsy. Coordinate submission at the MTFs and VA. Plan launch meeting at NMCSO when the project is fully approved for funding by the CDMRP Contract Specialist.

### ***3c: Review proposal ideas and provide feedback on outcomes design.***

Drafted an IRB template to integrate with proposal review procedures to ensure that protocols meet minimal BADER Consortium standards regarding outcomes variables and outcomes-related

methodology to send to each MTF to conduct focus groups at each site. The ROM is awaiting direction from the BADER Executive Committee about next steps.

***3d: Work with investigators to provide design measurement platforms and train research personnel.***

***3e . Develop new measurement techniques tailored for specific interventions as appropriate.***

Items 3d-e have not been applicable yet. Dr. Tulsy will be providing this level of support to Alison Linberg on her protocol that started October 1, 2013. Dr. Tulsy has been available to researchers at the MTFs and will work with investigators as needs arise.

## **Biostatistics Core: Christiana Care Health Systems (CCHS)**

The Biostatistics Core is run as fee-for-service core. During the first year, Core leadership developed the necessary policies and procedures related to accessing Core services. Forms were developed for formally requesting Core services and currently reside on the BADER Consortium website.

The Biostatistics Core is prepared to assist all investigator teams during the preparation of BADER Consortium project proposals. Key areas of assistance include experimental design (with an emphasis on comparative effectiveness studies), selection of statistical models, and performance of power analyses on existing pilot data.

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### **Task 1: Participate in development of project specific aims and research design with investigators.**

The Biostatistics Core realized a dramatic increase in engagement at the beginning of the second year. The BADER Consortium Call for Proposals resulted in five requests for statistical consultation. All requests included determining the appropriate statistical analyses, writing the statistical methods section of the proposal, and calculating sample size and power. All requests were completed with supporting documentation sent to the investigators before the proposal deadline (December 17, 2012). The Biostatistics Core was included in the budget of three of the five proposals, intended for statistical consultation during the proposed study if selected for funding.

The Biostatistics Core has been approached by one research group for support in the 2013 Call for Proposals.

### **Task 2: Develop statistical analysis plans (SAP) for each research project.**

Statistical analysis plans and sample size calculations were completed for five (5) of the protocols submitted for the 2012 Call for Proposals.

### **Task 3: Assist in the design of datasets for analysis. Provide transfer capabilities and expertise.**

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At this time, there have not been any requests from Consortium members for this service.

**Task 4: Conduct statistical analyses.**

The Administrative Core ran a “real” test case through the Biostatistics Core. The test case was used to identify key steps in and to model the Biostatistics Core consultation process. The core effectively developed and executed a complete statistical analysis and documentation plan for the test case “Change in Peak Joint Moments as a Function of Walking Speed and Body Weight Support” (PIs: Steven Stanhope; Saryn Goldberg).

This process revealed an additional step that requires the CCHS IRB to screen projects for prior IRB approval prior to receiving Biostatistics Core assistance. This is an important and necessary step to ensure that human subject protections are in place.

**Task 5: Provide assistance in developing presentations, writing reports and manuscripts.**

At this time, there have not been any requests from Consortium members for this service.

## Progress Reports on Clinical studies:

### **2012.1: “Improving Step-To-Step Control of Walking in Traumatic Amputees”** **“STEP2STEP”**

**Abstract:** Gait and balance training are essential for patients with lower limb amputation because of their high fall risk. However, little scientific evidence exists to guide efforts to develop such training programs. The purpose of this study is two-fold: to determine how step-to-step control strategies differ between patients with varying levels of amputation and to determine how these patients respond to a virtual reality based training intervention. Addressing these two issues will provide an essential foundation from which we can design more effective training protocols. Enhanced training will take place in a fully immersive virtual reality (VR) environment so we can apply well controlled and ecologically relevant motions to the walking surface. Effective VR-based gait training programs may provide significant advantages over traditional gait training, putting therapists in control of the training environment and allowing them to quantitatively monitor patient progress in real time. We expect this will yield significant generalization to real world walking. We will conduct a single-center study including 30 patients with varying degrees of lower limb amputation to determine the relative effects of VR based treatment on walking step-to-step control strategies. We will test each subject before, during, and after training as well as at an approximate 2-week follow-up while walking both in the VR environment and while walking over flat and uneven ground. Step-to-step control measures will then be compared across the group of patients using regression analyses against clinical performance measures to better understand the effects of physical ability on step-to-step control. Additional intra-subject analyses will be conducted to look at changes in walking over the course of the intervention.

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Title:	2012.1: “Improving Step-To-Step Control of Walking in Traumatic Amputees”	
Funded Amount:	\$679,300	
Principal Investigators:	Jonathan Dingwell, PhD	Department of Kinesiology & Health Education, University of Texas at Austin, Austin, TX
	Jason Wilken, PhD	Military Performance Lab, Center for the Intrepid, Department of Orthopaedics & Rehabilitation, Brooke Army Medical Center, San Antonio, TX
Collaborators:	Joseph P. Cusumano, Ph.D.	Pennsylvania State University, Department of Engineering Science & Mechanics

Accruals	No patients yet enrolled. All IRB approvals have been obtained to begin the Specific Aim #2 study. We just recently began recruiting subjects for Aim #2
IRB Approvals:	Our IRB application for Specific Aim #1 was determined to qualify for “ <u>exempt</u> ” status so therefore no annual renewals are required. Our IRB application for Specific Aim #2 has been “conditionally approved” by BAMC IRB and has received HRPO approval.
Amendments to IRB	We have submitted 1 new amendment to the IRB for Specific Aim #2. This amendment was submitted to the IRB on June 14 and its status is currently listed as “Pending Review”. This amendment included the following changes: <ul style="list-style-type: none"> <li>• To add Melinda Metzger-Abamukong (a BADER CRC Protocol and Data Management Coordinator) with the duties of recruitment, project coordination, data storage and organization</li> <li>• The role of Rosemary Wells (DoD employee) was extended to include consenting</li> <li>• The data collection window for participants was extended from 4 to 6 weeks to ensure we have enough time for all 12 visits to the lab; this timeline was updated on the protocol and consent forms</li> <li>• Updated the contact information and clarified the eligibility criteria on the recruitment flyer to match that of the protocol</li> </ul>
Adverse events:	None reported.
Serious adverse events:	None reported.
Problems or barriers to research:	None reported.

### Progress to date:

The project began in September 2012.

Dr. Jonathan Rylander (University of Texas Post-Doctoral Associate, hired Oct. 1, 2012) lives in San Antonio, TX and works full time at the Military Performance Lab (directed by Jason Wilken) at CFI / BAMC. Dr. Rylander has daily interactions with MPL and other CFI staff. Dr. Rylander helped to write, compile, and submit all of the IRB paperwork for the Specific Aim #2 intervention study for this project. These documents were submitted in December 2012 and were reviewed by BAMC IRB in January 2013. In parallel with these efforts, Dr. Rylander has begun acquiring the data and writing the analysis codes necessary to conduct the secondary data analyses described in Aim #1 of our original proposal. Dr. Rylander also makes occasional trips to Austin to coordinate with Dr. Dingwell. Dr. Rylander has maintained regular phone and email communications with Ms. Salinas.

Ms. Mandy Salinas (University of Texas Ph.D. student, hired Sept. 1, 2012) has been working on BADER-related activities part-time (5 hrs/wk) from Austin, TX. Ms. Salinas has been assisting Dr. Rylander with implementing and evaluating some of the data analysis methods.



Dr. Dingwell continues to travel to CFI / BAMC approximately once every 2-3 weeks for full-day meeting with Dr. Wilken, Dr. Rylander, and other project personnel to discuss progress.

Dr. Dingwell has met regularly with Ms. Salinas in Austin and continues to have regular phone call with Dr. Rylander in San Antonio to assess progress and discuss the project.

Dr. Dingwell also continues to maintain regular discussions of theoretical and computational issues with Dr. Joseph Cusumano at Penn State University.

### **Specific Aim #1:**

To quantify the extent to which patients with transtibial amputation exhibit step-to-step control strategies that are different from appropriately matched non-impaired control subjects.

- (a) This project involves secondary analyses of previously collected data. We have now extracted all of the relevant stride parameters (stride lengths, times, width, etc.) from the original data. We have run multiple analyses on those stride data and have cross-checked our results to ensure the highest degree of accuracy. We have set out a plan to publish these results in 3 separate manuscripts. Dr. Rylander will lead 2 and Ms. Salinas and Dr. Dingwell will lead the 3<sup>rd</sup>. Dr. Rylander is currently drafting the first manuscript. The first manuscript focusing on extending the GEM analyses to the frontal plane, the second focusing on applications of these analyses to perturbed walking in healthy subjects, and the third focusing on applying these analyses to walking in patients with lower extremity perturbations during both un-perturbed and perturbed walking. We anticipate these manuscripts to be submitted for publication approximately in Spring, Summer, and Fall of 2013, respectively.
- (b) The next steps are to finalize and submit the first manuscript, and then finalize the analyses and start writing the 2<sup>nd</sup> and 3<sup>rd</sup> manuscripts.
- (c) (i): We have faced no “administrative” challenges as of yet.  
(ii): The first “scientific” challenge we had was determining how to best identify heel strike events to we could obtain highly accurate stepping parameter data. This challenge has now been solved / resolved.  
(iii): The second “scientific” challenge we had was to extend our use of sagittal plane (stride *length* vs. stride time) GEM-based analysis tools to the frontal plane (i.e., stride *width* vs. stride time). We believe we have now resolved these issues as well.

### **Specific Aim #2:**

To determine if a VR based gait re-training intervention that explicitly exploits each patient’s own step-to-step control is more successful than VR based gait stability training and/or conventional therapy for improving walking in patients with transtibial amputation.

- (a) We received final IRB and HRPO approvals April 15, 2013. Dr. Rylander and Dr. Wilken spent a great deal of time over the summer working very closely with Military Performance Laboratory (MPL) staff to finalize protocol details and recruitment strategies. We are currently actively recruiting for subjects.
- (b) Our next steps are to begin data collection and analyses.

- (c) (i): Our primary “administrative” challenge the past 3-6 months has been finding qualified and willing participants. This intervention study involves a long and involved protocol. There are multiple other studies going on in the MPL and the number of new patients coming into BAMC has declined in recent months.
- (d) (i): Dr. Wilken is working very hard with his staff and with the clinical staff at CFI to identify potential participants and recruit them into the study. The team will work with BADER on the subject recruitment initiative.

### **Preliminary Results:**

Dr. Cusumano and Dr. Dingwell did a comparison / analysis of previously collected and previously published results. These included comparisons of measures of stride-to-stride fluctuation dynamics for overground walking, treadmill walking without optic flow, and treadmill walking with optic flow. These data provide preliminary insights into how different perceptual inputs in these different walking contexts affect how people regulate their stepping movements from each step to the next. These analyses were submitted to the “*Dynamic Walking*” and “*Neuroscience*” conferences.

Dr. Rylander has also completed most of the data analyses for Aim 1. This work compared the frontal (coronal) plane stepping control strategies of patients with unilateral transtibial amputation to those of healthy controls. All subjects walked with either no perturbations, mediolateral *visual* field perturbations, or mediolateral treadmill *platform* perturbations. Both subject groups corrected deviations in the stride-to-stride *changes* in lateral foot placement, but not deviations in their absolute lateral *position* on the treadmill. These stride-to-stride changes in foot placement became significantly more anti-persistent during perturbed walking in both groups. Patients with amputation exhibited significantly greater variance in their stride-to-stride corrections across all conditions, but particularly during platform perturbations. Thus, although patients with amputation appeared to adopt the same overall control strategy as healthy controls, they were less successful at implementing it. These results will be presented at the *Neuroscience* conference in November, 2013.

Following up on both sets of findings listed above, Dr. Rylander then also analyzed and directly compared the responses of patients with amputation to those of able-body subjects to visual perturbations using several different measures related to maintaining lateral balance, including measures of step width (SW) variability, lateral margins of stability (MOS), and detrended fluctuation analysis (DFA) (a measure of stride-to-stride control). Surprisingly, no significant differences were found between patients and able-body groups for how much each of these measures *changed* when subjects switch from non-perturbed to visually perturbed walking. Although subjects in both groups responded strongly to the visual perturbations themselves, subjects in both groups responded similarly to these visual perturbations. It is often assumed that limb loss, and the associated loss / disruption of proprioceptive feedback will lead these patients to rely far more heavily on visual feedback to regulate walking movements. Our results indicate that this is not true, and that in spite of the loss of distal limb sensation and limb function, otherwise healthy and active persons with unilateral trans-tibial amputation do not depend more on visual field information than healthy able bodied controls. These results were submitted to the 2014 *Orthopaedic Research Society* conference.

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Presentations (BADER-related):

Cusumano, J.P. and Dingwell, J.B. (Submitted) "On the Role of Perception in Regulating Stride-To-Stride Walking Dynamics," ***Proceedings of the 2013 Dynamic Walking Meeting***, Pittsburgh, PA, June 10-13, 2013.

Rylander, J.H., Wilken, J.M., Cusumano, J.P. and Dingwell, J.B. (2013) "Coronal Plane Treadmill Stepping Control Strategies in Individuals with Transtibial Amputation," ***Proceedings of the 43rd Annual Meeting of the Society for Neuroscience***, San Diego, CA, November 9-13, 2013.

Dingwell, J.B. and Cusumano, J.P. (2013) "Using Perceptual Cues to Regulate Walking From Stride-To-Stride," ***Proceedings of the 43rd Annual Meeting of the Society for Neuroscience***, San Diego, CA, November 9-13, 2013.

Rylander, J.H., Beltran, E.J., Wilken, J.M., and Dingwell, J.B. (Submitted) "Healthy Persons with Unilateral Amputation and Able Bodied Controls Respond Similarly To Visual Field Perturbations While Walking," ***Proceedings of the 60<sup>th</sup> Annual Meeting of the Orthopaedic Research Society***, New Orleans, LA, March 15-18, 2014.

## **2012.2 “Return to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”** **“RETRAIN”**

**Abstract:** Lower extremity amputations significantly impact a soldier’s gait function and their ability to return to active duty. Despite standard rehabilitative care that includes gait training, loading remains elevated in the intact extremity, increasing the risk for the development of degenerative joint disease. *The purpose of this study is to examine whether symmetry of loading can be improved in both walking and running using real-time feedback in individuals with unilateral, transtibial amputations.*

Title:	2012.2 “Return to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”	
Funded Amount:	\$708,524	
Principal Investigators:	Irene Davis, PhD, PT	Spaulding Rehabilitation Hospital
	Alison Linberg, DPT, ATC	Walter Reed National Military Medical Center
Collaborators:	Eveline Graf, PhD	Spaulding Rehabilitation Hospital
	Devjani Saha, PhD	Walter Reed National Military Medical Center (BADER CRC staff)
	Cynthia Samaan, MS	Spaulding Rehabilitation Hospital
	Amanda Wingate, BA	Walter Reed National Military Medical Center (BADER CRC staff)
Accruals	We have just received IRB Approval. We have identified two individuals we will be contacting to screen as subjects.	
IRB Approvals:	<b>SNRC:</b> IRB approval received: June 13, 2013 HRPO approval received: June 19, 2013 <b>WRNMMC:</b> IRB approval received: June 19, 2013 HRPO approval received: July 11, 2013	
Amendments to IRB	<b>SNRC</b> Amendment 1 (submitted 06/02/13; approved 06/13/13) a. Inclusion of subjects with non-traumatic amputation (except dysvascular amputation) b. Addition of heel raise protocol to prepare subject for running portion c. Addition of Illinois agility test as a functional measure for running d. Non-identifiable data will be shared with BCTDB  Amendment 2 (submitted 07/19/13; approved 08/08/13)  a. Removed Nike as study sponsor	

	<p>b. Addition of question to telephone script (year of amputation)</p> <p>c. Addition of anthropometrical measurements</p> <p>Amendment 3 (submitted 09/03/13; approved 10/02/13)</p> <p>Separate protocols for walking and running.</p> <p><b>WRNNMC</b> Submitted 6/21/13. Approved 7/18/13.</p> <p>Clarified inclusion criteria and changed testing from CAREN treadmill to the Bertec treadmill.</p> <p>NIKE, who originally committed to providing footwear, has now decided not to be involved (no reason provided). Nike did provide us with the SDK to access the data from their insole that we will be pilot-testing.</p>
Adverse events:	None reported.
Serious adverse events:	None reported.
Problems or barriers to research:	While encouraged by the HRPO to pursue becoming the IRB of record for project 2012.2, the researchers met a significant roadblock with the approval of an Interagency Authorization Agreement. They were advised by HRPO for both Spaulding and WRNNMC to each submit separate IRB documentation to their respective institutions. This set the beginning of the project back as the IRB documentation needed to be revised and resubmitted the local IRB.

Preliminary results/progress to date:

- Met with staff at WRNNMC to develop the necessary protocol documentation for the IRB.
- Recruited project staff.
- Wrote data collection protocols for the project, along with a lab manual of the procedures.
- Engaged the Biomechanics Core to develop the feedback software to be utilized in the study for both the walking and the running retraining.
- Engaged Simbex, who will assist with the mobile monitoring devices needed to monitor progress during follow-up.
- Boston and Providence VA hospitals have been contacted regarding recruitment of subjects.

- Custom Marker Alignment Device (MAD) was developed and tested – we are presenting a podium at the American Society of Biomechanics on its reliability and validity.
- 2<sup>nd</sup> MAD constructed and sent to WRNMMC
- Real time feedback programs were piloted for both walking and running at both SNRC and WRNMMC
- Analysis software suite written and tested
- Two day visit to WRMMC to ascertain consistencies in data collection processes
- Planning for the harness system to be installed above the treadmill.
- Completing the writing of our analysis software
- WRNMMC and we have each recently received a sample pair of the Nike shoe and insoles to conduct initial testing with.

Aim 1. To determine if a program of gait retraining using realtime kinetic feedback in soldiers with unilateral, transtibial amputations alters the asymmetry of gait during walking and running

Aim 2. To determine whether functional outcomes are altered with gait retraining during walking and running

a. Following a prolonged IRB process that began in June, 2012, we received approval for aims 1 and 2 in July 2013. This delay has put us nearly 1 year behind which we expect will necessitate a 1 year, no cost extension to complete aims 1 and 2. We have worked to refine our feedback program as well as to develop a marker placement device needed to improve the reliability of our repeated kinematic measures.

b. We are now actively recruiting for the study.

c. Recruitment has been slow. Therefore, we have invited local prosthetists to observe the type of feedback we provide the potential participants. We have advertised in the Spaulding Adaptive Sports Newsletter. We have also participated in the amputee running clinic held at Harvard University that was sponsored by the Challenged Athletes Foundation. We are going to be placing an advertisement in the online version of the Boston Globe. Finally, we are currently in contact with the New England Amputee Association, an associate with the Amputee Coalition, a national organization.

Aim 3. To determine whether symmetry of loading and functional outcomes are influenced by the provision of feedback during community walking and running using a mobile monitoring device.

a. NIKE has now agreed to supply the instrumented insole for feedback and has provided us the software development kit in order to access the data for our purposes.



b. We are currently in contact with Sapient, a software development company, who will develop the mobile application needed to conduct our pilot study to validate the insole with the instrumented treadmill data. Steve Jamison, a member of the BADER Clinical Research Core will be join our staff in November, will be heading this initiative.

The following activities were to take place in the first year of the grant period. However, due to the delay in the approval of the project, the IRB process, which was to begin in the first year of the consortium, did not begin until 9 months into this year. The IRB process was significantly delayed and both sites were unable to begin recruitment until near the end of the second year. Therefore, we are approximately 1 year behind. The following activities of our timeline will take place in year 2 of the grant:

- Baseline gait analysis and outcome measures
- 8 Sessions of walking gait retraining
- Post-training gait analysis and outcome measures
- 1 mo. follow-up gait analysis and outcome measures
- 8 Sessions of running gait retraining
- Post-training gait analysis and outcome measures
- 1 mo. follow-up gait analysis and outcome measures
- Pilot study with instrumented shoe

The following activities of our timeline will take place in year 3 (no cost extension will be requested) of our timeline:

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- Completion of Retraining
- Comparison of walking variables across time
- Comparison of running variables across time
- Data Dissemination
- Prepare RCT for submission to DoD/NIH

#### Abstracts:

Samaan, C, Schwartz, J, Graf, E, Davis, IS and Rainbow, MJ. A standing alignment system improves between-session repeatability in gait kinematics: a preliminary study. Presented at the American Society of Biomechanics Meeting, Omaha, Nebraska, September 2013.

**2012.3: A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma**

***“Trauma Outcomes”***

Title:	2012.3: A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma	
Funded Amount:	Funded through Research Outcomes Measurement Core budget	
Principal Investigator:	David Tulskey, PhD	New York University
Collaborators:	Erik Wolf, PhD	WRNMMC
	Marilynn Wyatt, MPT	NMCSD
	Jason Wilken, PhD	BAMC/CFI
Accruals	No patients yet enrolled	
IRB Approvals:	NMCSD IRB approval received (August 21, 2013). Pending HRPO approval.	

**Details of this project can be found under Research Outcomes Measurement Core Statement of Work, Task 2**

## **2013.1: Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?**

### ***“The ProLegRx Study”***

***This project was slated to begin October 1, 2013. At this time, we have not received funding approval from the Contract Specialist.***

**Abstract:** There are currently no science-based, objective methods for optimizing running-specific prosthesis (RSP) prescription. Existing practices can waste time, money, and resources and do not necessarily provide the best prosthetic prescription. Due to the severity of impairment caused by a leg amputation and the healthcare costs sustained over the lifetime of a person with an amputation, it is extremely important to improve RSP prescription so that Soldiers and Veterans with amputations can regain the greatest possible level of functional ability and return to active duty, if they choose. Our goal is to develop tools for clinicians to prescribe running-specific leg prostheses that facilitate optimal function for Soldiers and Veterans with transtibial amputations. We intend to systematically vary the stiffness and height of distance-running RSPs and measure the biomechanical and metabolic effects of running at the speed required for a subject's age/sex 50<sup>th</sup> percentile Physical Fitness Test (PFT) 2 mile run and at one standardized speed, 3 m/sec. We also intend to systematically vary the stiffness and height of sprint-running RSPs and measure the biomechanical and performance effects of running across a range of speeds. Then, we will combine results from distance-running and sprint-running prostheses to develop clinically relevant, quantitative algorithms for prosthetic stiffness and height prescription based on a subject's weight, amputation level, limb segment lengths, and desired running speed. The results of our research will be disseminated to clinicians and will improve RSP prescription for people with leg amputations. We hope to improve and expedite rehabilitation for Soldiers and Veterans with transtibial amputations and to save time, money, and resources. Optimizing RSP prescription would facilitate aerobic conditioning, reduce injury risk, improve running economy (the metabolic demand at a given running speed) and improve performance; thus improving the quality of life and reducing the healthcare needs of Soldiers and Veterans with leg amputations.

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Title:	2013.1: Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?	
Funded Amount:	\$882,827	
Principal Investigator:	Alena Grabowski, PhD	Dept. of Veterans Affairs Eastern Colorado Healthcare System
Collaborators:	Rodger Kram, PhD	Dept. of Integrative Physiology, University of Colorado
	Ryan Stephenson, MD	Dept. of Veterans Affairs Eastern Colorado Healthcare System
	Michael Litavish, CP	Dept. of Veterans Affairs Eastern Colorado Healthcare System

## **2013.2: Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators**

### ***“The K2POWER study”***

***This project was slated to begin October 1, 2013. At this time, we have not received funding approval from the Contract Specialist.***

**Abstract:** Advances in lower limb prostheses have allowed for improvements in function and participation in activities for individuals with transtibial limb loss. Advancements in passive ankle prostheses are still limited in their ability to assist with forward progression and push-off because of their inability to produce positive network. Recent advancements to powered prostheses have proposed the potential to provide positive network, returning these individuals to a level of function and efficiency similar to those without limb loss. The objectives of this proposal are to identify differences in gait, efficiency, function, and quality of life between using a standard passive prosthesis versus a powered ankle prosthesis, and to see if changes remain stable for up to six months after the initial fitting. We wish to address these objectives in individuals with lower limb loss that are not capable of fully interacting in their environment and community. This proposed project will assist with prosthetic prescription decisions regarding individuals with transtibial limb loss with varying levels of function, as advanced technology is often not directed at the more disabled population, despite these individuals potentially having the most to gain from this technology.

Twenty individuals with transtibial limb loss will be recruited to participate in this longitudinal study: ten who function at a Medicare Functional Classification Level (MFCL) K2-level and ten who function at a MCFL K3-level. Participants will be evaluated in their current passive ankle prosthesis, be fit with a powered ankle prosthesis, and be followed during six visits over six months. Testing during these six months will include analyzing how the participants walk, how much energy they are using to walk, their balance and endurance, and subjective reports of how they feel and what they are able to do in the prosthesis. We expect results will show differences in walking measures that indicate a change in risk of secondary injury to the intact limb, such as osteoarthritis; will identify changes in efficiency with walking and in balance and endurance; and will measure the users satisfaction with the device and how the user is able to interact with his/her home and community lives, to indicate differences in ability to re-integrate into these roles.

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Title:	2013.2: “Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators”	
Funded Amount:	\$1,529,718	
Principal Investigator:	Alison A. Linberg, DPT	Walter Reed National Military Medical Center
Collaborators:	Erik J. Wolf, PhD	Walter Reed National Military Medical Center
	Joseph B. Webster, MD	Hunter Holmes McGuire VA Medical Center
	David S. Tulskey, PhD	New York University

### **2013.3: Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma**

#### ***“QOL Toolbox”***

***This project was slated to begin October 1, 2013. At this time, we have not received funding approval from the Contract Specialist.***

**Abstract:** As a result of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND), an unprecedented number of wounded warriors have had combat-related major traumatic limb injuries that include amputation of one or more limbs. These wounded warriors are typically treated for long periods of time at Military Treatment Facilities (MTF) within the Department of Defense (DoD) and later, upon discharge from active duty, at Department of Veterans Affairs Medical Centers (VA) or civilian hospitals. Unfortunately, the health care that is provided across the DoD MTF sites and the VAs is not well coordinated. Individual clinicians and researchers use a wide variety of measurement tools to assess their patients and the lack of standardization across sites makes it difficult to track progress or compare functioning and outcomes across the major treatment facilities. This often results in a lack of coordination of medical care. From a research perspective, the lack of uniformity in measurement tools makes it difficult to compare patients across studies or follow individuals over time as they are transferred to and receive care from different medical facilities. This hinders our ability to study these injured service persons over time to better understand their course of recovery and identify the most effective types of treatments. Because upper limb injury was a rare occurrence prior to OEF/OIF/OND there have been few studies on this patient group and little evidence to inform the design of optimal clinical care guidelines.

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People who have had upper extremity amputation of one or both hands and/or arms, major traumatic damage to their limbs without amputation, or who have had multi-limb amputations are understudied groups. When research is performed, the medical community has focused on assessment of patient physical functioning (e.g., limitations in an individual's strength and their ability to walk and stand) and placed less emphasis on measuring the injured individual's ability to return back to a healthy and productive life by participating in society, and resuming work and social relationships (known as community reintegration). Entire areas of functioning revolving around social participation have been largely ignored in clinical practice. Moreover, without coordination between the MTFs, the VAs, and civilian hospitals, researchers and clinicians at the different sites will use different measures, making it very difficult to accumulate data across sites. A coordinated approach to assessment for this population would help improve clinical care and allow research at different sites to be aggregated. This grant hopes to improve all of these things.

A central aim of this grant is to develop a “toolbox” of outcome assessments that is comprehensive and includes measures of community integration and quality of life, as well as assessments of physical activity and limitations in body functions. The proposed study is unique because it brings together a large group of clinicians and researchers from the major military treatment facilities that treat individuals with traumatic amputation (i.e., the Center for the Intrepid/San Antonio Military Medical Center, Naval Medical Center in San Diego, Walter Reed National Military Medical Center) and one of the largest VA

hospitals and amputation centers (Tampa VA) and one of the oldest and largest civilian hospitals (Rusk Rehabilitation at New York University) along with leaders in measurement from the University of Michigan and Providence VA. This grant will bring together a diverse team of stakeholders (individuals who have had catastrophic limb trauma, clinicians, policy makers, and research investigators) with many representatives from our participating sites to discuss and agree on a series of common measures and scales that can help bring standards and uniformity to the field.

Given the dearth of research on individuals with upper extremity amputation, we plan to validate the toolbox by administering the upper extremity toolbox measures to individuals who have had upper limb amputation at 3 MTFs, a VA, and a civilian hospital. The instrument will be reassessed to help us ascertain reliability and other psychometric properties. Through this collective work we will introduce a new level of cooperation and uniformity to the field. We will study individuals with upper extremity amputations, a subgroup of injured service people who have been underrepresented in research in the past. We will also emphasize the vital areas of community reintegration and quality of life assessment with MTF and VA clinical practice to improve the lives of individuals who have had these traumatic limb injuries. These efforts will ultimately result in improvements to clinical practice which will directly benefit persons with both combat and non-combat related limb trauma and amputation.

Title:	2013.3: "Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma"	
Funded Amount:	\$1,999,969	
Principal Investigator:	David Tulskey, PhD	New York University
Collaborators:	Erik Wolf, PhD	WRNMMC
	Jason Wilken, PhD	BAMC/CFI
	Marilynn Wyatt, MPT	NMCSD
	Tamara Bushnik, PhD	NYU Langone Medical Center
	Linda Resnik, PT, PhD	Providence VA Medical Center
	Gayle Latlief, DO	James A. Haley Veteran's Hospital, Tampa FL
	Claire Kalpakjian, PhD	University of Michigan
	Pamela Kisala, MA	New York University



**KEY RESEARCH ACCOMPLISHMENTS**  
**FOR THE PERIOD**  
**SEPTEMBER 30, 2011 – SEPTEMBER 29, 2013**

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**BADER Consortium**

**W81-XWH-11-2-0222**

**Annual Report – Year 2**

**Key Research Accomplishments**

**Key Accomplishments in the second year of performance (September 30 2012 – September 29 2013):**

- Approval of three additional BADER funded research projects bringing the total to 5:
  - Project 2012.2 – Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback.
  - Project 2012.1 – Improving Step-To-Step Control of Walking in Traumatic Amputees.
  - Project 2013.1 – Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?
  - Project 2013.2 - Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators.
  - Project 2013.3 - Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma.
- Recruited all eight BADER funded positions at the MTFs
- Provided research support to nine on-site MTF research projects.
- IT and videoconference infrastructures
- Continue to increase the ranks of BADER Consortium Affiliates (n=96)
- Support NMCS D with use of UD Power Segment technique
- Streamlined the IRB approval process by establishing blanket Institutional Award Agreement (IAA).
- In concert with the MTFs, began development of a central research subject repository.
- Held the first BADER Consortium annual meeting.
- Providing valuable research support through Consortium funded on-site employees.
- On-boarded multiple agencies to the omnibus CRADA to reduce administrative hurdles and allow rapid execution of research studies.
- Established a research related travel support policy and supported travel expenses for collaborators to visit MTF sites and two MTF personnel to present at the American Society of Biomechanics (ASB) scientific meeting.
- Supporting multiple proposals for external funding.
- Strengthen research collaborations and partnerships between MTFs, VA and research focused institutions.
- The live instance of the NIH supplied Protocol and Data Management System (PDMS) is up and running on BADER servers.

- Development of table and announcement for alternative project funding models.
- Strategizing with NIH officials.
- Outreach and meetings with VA.
- BADER Consortium Web-site development continues:
  - Secure log-in to the website completed
  - Core services request form completed
  - Additional enhancements being explored

**Key Accomplishments in the first year of performance (September 30 2011 – September 29 2012):**

- Approval and establishment of two clinical research projects
- HRPO clearance and start of first project (Dingwell)
- Initiated the development of first IRB of record outside the MTFs (Davis)
- Initiated the development of partnership with Nike, USA (Davis)
- Development and implementation of an Omnibus Cooperative Research and Development Agreement (CRADA)
- Established a consortium-wide protocol and data management system
- Partnered with the DoD and VA's Extremity Trauma and Amputation Center of Excellence (EACE)
- Worked with the EACE to develop research focus (gap) areas for the BADER Consortium call for proposals
- Established a complete process for the call, submission, review and selection of Consortium funded projects
- Published the BADER Consortium call for clinical research proposals
- Established the BADER Consortium web site and standard operating procedures (SOPs)
- Initiated the hiring of eight research support staff to be placed onsite at MTFs.
- Open communication with all MTFs and partners through bi-weekly teleconferences
- Established partnerships with the VA and NIH

**REPORTABLE OUTCOMES**  
**for the period**  
**September 30, 2011 – September 29, 2013:**

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## **Research Projects:**

### BADER Funded Projects:

Dingwell, J., and Wilken, J. **“Improving Step-To-Step Control of Walking in Traumatic Amputees”** \$679,300. Sites: University of Texas Austin, Brooke Army Medical Center/Center for the Intrepid.

Davis, I., and Linberg, A. **“Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”** \$708,524. Sites: Spaulding Rehabilitation Hospital, Walter Reed National Military Medical Center.

Grabowski, A., Kram, R., Stephenson, R., Litavish, M. **“Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?”** \$882,827. Sites: Eastern Colorado Healthcare System – Department of Veterans Affairs, Jewell Regional Amputation Clinic.

Linberg, A., Wolf, E., Webster, J., Tulskey, D. **“Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators.”** \$1,529,718. Sites: Walter Reed National Military Medical Center, Hunter Holmes McGuire VA Medical Center.

Tulskey, D., Wolf, E., Wilken, J., Wyatt, M., Bushnik, T., Resnik, L., Latlief, G., Kalpakjian, C., Kisala, P. **“Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma.”** \$1,999,969. Sites: New York University, University of Michigan, Walter Reed National Military Medical Center, Brooke Army Medical Center/Center for the Intrepid, Naval Medical Center San Diego, NYU Langone Medical Center, Providence VA Medical Center, James A. Haley Veterans Hospital, Tampa FL.

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### BADER Scientific Technical Core Supported projects:

Tulskey, D., Wyatt, M., **“A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma.”** Sites: University of Michigan, Naval Medical Center San Diego, Brooke Army Medical Center/Center for the Intrepid.

### Externally Funded Projects Supporting BADER Activities or Supported by BADER:

Gillespie, J., et al. **“Rapid Prototyping of Advanced Passive Dynamic Ankle-Foot Orthoses Designs for Wounded Warriors.”** \$3,000,000. Sites: University of Delaware. Funded by: DARPA

Whittelsey, S., Selbie, W.S. **“Development of a Low Cost, Real-time Biofeedback Gait Retraining System”** \$149,995. Funded by: NIH, Phase I – SBIR.

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Kaufman, K. **“Comparison of 3-D Gait Analysis Data Across Department of Defense Sites.”** Funded by: Center Rehabilitation Sciences Research (CRSR). Support by Biomechanics Scientific Technical Core.

Deluzio, K.J., Selbie, W.S., **“Statistical Models for Establishing a Control Data set for Biomechanical Gait Analysis”** \$25,000. Natural Sciences and Engineering Research Council of Canada.

Pending Proposals for External Funding Supported by BADER:

Morshed, S., Kaufman, K. **“The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees”** Proposal to CDMRP/PRORP, July 2013.

Judkins, T. **“Development of a Mobile Advanced Real-Time Kinetic System (MARKS) for Balance Rehabilitation.”** Proposal to Department of Defense SBIR, June 2013.

Ziemke, G., Campello, M. **“A pilot study to test the efficacy of psychologically based physical therapy training for treating deployed US Sailors and Marines with musculoskeletal injuries.”** Proposal to CDMRP/PRORP, July 2013.

Van Citters, D. **“Active Implant”** Proposal to CDMRP/PRORP, July 2013.

Research Proposals - BADER Supported

Ziemke, G. **“Rate of Surgical Revision in Active Duty Service Members After Anterior Cervical Disc Arthroplasty or Fusion for Spinal Post-Traumatic Osteoarthritis”**. CDMRP/PRORP pre-application, not invited for full submission.

Ziemke, G. **“Identifying Obstacles and Facilitators of Work Re-Integration in Active Duty Sailors and Marines with Deployment and/or Combat-Related Musculoskeletal Injuries.”** CDMRP/PRORP pre-application, not invited for full submission.

Buchanan, T. **“OA study.”** CDMRP/PRORP pre-application, not invited for full submission.

The BADER Consortium Administrative Core supported, at their request, the VA with planning the upcoming, DEKA arm multi-center clinical trial.

The MTF/BADER Consortium limb salvage team submitted an unfunded pre-proposal to the PRORP TRPA program.

Dr. Tim Judkins with Intelligent Automation, Inc. has completed a DoD funded Phase I SBIR, Virtual Therapist PTSD, project and wishes to develop and execute the Phase II, clinical trial effort, through the BADER Consortium.



MTF Research Projects Supported by CRC Staff:

Adaptation Study	WRNMMC	CRC Staff (Saha)
OA Project	WRNMMC	CRC Staff (Saha)
Trunk	WRNMMC	CRC Staff (Saha)
BL (case report)	BAMC/CFI	CRC Staff (Jamison)
RE	BAMC/CFI	CRC Staff (Jamison)
AFOR	BAMC/CFI	CRC Staff (Jamison)
RG	BAMC/CFI	CRC Staff (Jamison)
AF	BAMC/CFI	CRC Staff (Jamison)
Level Belt Validation	OSU/(Boston)	CRC Staff (Jamison)
EACE P2M	BAMC/CFI	CRC Staff (Metzger-Abamukong)
MPL	BAMC/CFI	CRC Staff (Metzger-Abamukong)
Rehab Effectiveness	BAMC-CFI/WRNMMC	CRC Staff (Metzger-Abamukong and Amanda Wingate)
Visual Feedback	WRNMMC	CRC Staff (Amanda Wingate)
Weight Shifting	WRNMMC	CRC Staff (Amanda Wingate and Devjani Saha)
CHAMP	WRNMMC	CRC Staff (Amanda Wingate)

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**Manuscripts, abstracts, presentations**

**BADER Funded Projects**

***Publications:***

None at this time.

***Abstracts:***

- Cusumano, J.P. and Dingwell, J.B. (2013) "On the Role of Perception in Regulating Stride-To-Stride Walking Dynamics," ***Proceedings of the 2013 Dynamic Walking Meeting***, Pittsburgh, PA, June 10-13, 2013.
- Rylander, J.H., Wilken, J.M., Cusumano, J.P., and Dingwell, J.B. (2013) "Coronal Plane Treadmill Stepping Control Strategies in Individuals with Transtibial Amputation," ***Proceedings of the 43rd Annual Meeting of the Society for Neuroscience***, San Diego, CA, November 9-13, 2013.
- Dingwell, J.B., and Cusumano, J.P. (2013) "Using Perceptual Cues to Regulate Walking From Stride-to-Stride," ***Proceedings of the 43rd Annual Meeting of the Society for Neuroscience***, San Diego, CA, November 9-13, 2013.
- Samaan, C., Schwartz, J., Graf, E., Davis, I., and Rainbow, M.J. (2013) "A Standing Alignment System Improves Between-Session Repeatability in gait Kinematics: A Preliminary Study," ***Proceedings of the Annual Meeting of the American Society of Biomechanics***, Omaha, NE, September 4-7, 2013

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***Patents:***

None at this time

**BADER Supported Projects**

***Publications:*** None at this time.

***Abstracts:*** None at this time.

***Patents:*** None at this time.

## **BADER Related Projects**

### ***Publications:***

- Takahashi KZ, Kepple TM, Stanhope SJ. A unified deformable (UD) segment model for quantifying total power of anatomical and prosthetic below-knee structures during stance in gait. *Journal of Biomechanics* 2012;45:2662-2667. PMID:22939292
- Schrank E and Stanhope SJ. Dimensional accuracy of ankle-foot orthoses constructed by an automated fit customization and rapid manufacturing framework. *Journal of Rehabilitation Research & Development* 2011;48(1):31-42. PMID:21328161
- Schrank ES, Stanhope SJ. Orthotic Device Research. In *Full Stride: The Past, Present, and Future of Lower Extremity Gait Systems*. Springer Publishing. *in preparation*.

### ***Abstracts and Presentations:***

- Schrank ES, Higginson JS, Stanhope SJ. A Repeatable and Predictable method to Rapidly Manufacture Function-Customized Passive-Dynamic Ankle Foot Orthoses. **Proceedings of the ASME**, 2012
- Razzook A, Gleason C, Willy R, Fellin R, Davis I, Stanhope S. Average Ankle Dynamic Joint Stiffness During Heel Strike Running. **(Proceedings) American Society of Biomechanics**, 2012
- Takahashi KZ, Stanhope SJ. Net Efficiency of the Combined Ankle-Foot System in Normal Gait: Insights for passive and Active Prosthetics. **(Proceedings) American Society of Biomechanics**, 2012
- Schrank ES, Higginson JS, Stanhope SJ. Compensatory Muscle Control Strategies when Walking with a Customized PD-AFO. **(Proceedings) American Society of Biomechanics**, 2011
- Takahashi KZ, Razzook AR, Guinn LD, Schrank ES, Kepple TM, Stanhope SJ. Unified Deformable Segment Model of the Combined Ankle-Foot System that Does Work. **(Proceedings) American Society of Biomechanics**, 2011
- Guinn LD, Takahashi KZ, Razzook AR, Schrank ES, Stanhope SJ. A proposed method for PD-AFO stiffness prescription procedure. **(Proceedings) Center for Biomedical Engineering Research Symposium**, University of Delaware, 2011.
- Guinn LD, Takahashi KZ, Razzook AR, Schrank ES, Stanhope SJ. Ankle Pseudo-Stiffness is Greatest During Gait Initiation. **(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.
- Razzook AR, Takahashi KZ, Guinn LD, Schrank ES, Stanhope SJ. Predictive Model for Natural Ankle Stiffness During Walking: Implications for Ankle Foot Orthosis Prescription. **(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.
- Takahashi KZ, Razzook AR, Guinn LD, Schrank ES, Stanhope SJ. A Model of Normal Gait Roll-Over Dynamics One Step Closer to Customizing Prosthetic Ankle-Foot Components. **(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.

- Khattri NS, Tierney JJ, Yarlagadda S, Shevchenko N, Gillespie JW, Schrank ES, Stanhope SJ. Carbon fiber based custom orthoses for augmenting net ankle moment in gait. (Proceedings) **Society for the Advancement of Material and Process Engineering**, 2013.

**Patents:**

None at this time.

**Informatics such as databases and animal models:**

The Consortium, through the Clinical Research Core, has executed a Collaboration Agreement with the National Institute of Child Health and Human Development (NICHD) for partnering on the use of the NICHD Clinical Trials Data Base (CTDB) as the Consortium PDMS system. This unique partnership is supported by leadership at both NIH and UD and brings substantial opportunities to both parties for future development and now offers the Consortium a secure and dedicated instance of the NIH Clinical Trials Database.

**Funding applied for based on work supported by this award:**

Morshed, S., Kaufman, K. “**The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees**” Proposal to CDMRP/PRORP, July 2013.

Judkins, T. “**Development of a Mobile Advanced Real-Time Kinetic System (MARKS) for Balance Rehabilitation.**” Proposal to Department of Defense SBIR, June 2013.

Ziemke, G., Campello, M. “**A pilot study to test the efficacy of psychologically based physical therapy training for treating deployed US Sailors and Marines with musculoskeletal injuries.**” Proposal to CDMRP/PRORP, July 2013.

Van Citters, D. “**Active Implant**” Proposal to CDMRP/PRORP, July 2013.

**Employment or research opportunities applied for and/or received based on experience/training supported by this award:**

Trevor Kingsbury, a biomechanist in the gait analysis laboratory at NMCSD. Currently holds a BS in Bioengineering from UC San Diego and a MA in Kinesiology with an emphasis in Biomechanics from San Diego State. Planning to apply to the University of Delaware Biomechanics and Movement Sciences PhD program under the BADER Consortium waived tuition program.

## CONCLUSION

As we complete year 2, efforts continue to be focused on the “Engagement” phase of the Consortium and working toward successful accomplishment of tasks as outlined in the proposed statement of work.

The Consortium has experienced a number of successes over the first two years. The partnerships with the MTFs are strengthening, the relationship with EACE is strong and the VA is actively engaged with the Consortium. The first two research projects are underway and have started recruitment of human subjects. The three projects selected in the first call for proposals cycle are in the process of contract negotiations with CDMRP and are actively seeking IRB and HRPO approval. In addition, plans for establishing administrative, personnel, IT and support infrastructures are on schedule or have been fully realized.

Over the first two years of performance, we have run into a few rate limiting factors which may impact the success of the Consortium.

- The IRB approval process is lengthy and follows a “learn as you go” model. The Clinical Research Core is working diligently to thoroughly model and streamline the IRB/HRPO approval process.
- Administrative approvals from CDMRP. Despite the GSC approval in March 2013, contract negotiations with the Contract Specialist at CDMRP are still not completed which has delayed the start of the three recently approved research projects. The requested materials were submitted on August 5, 2013 however, we have yet to receive approval to move forward. Given this delay, to complete the proposed projects, we will likely require a no-cost-extension.
- Human Subject Recruitment. Our MTF partners have informed us that as the current conflicts come to a close, the number of wounded service members is declining drastically. While this is a very good thing, it has a significant impact on the existing MTF subject recruitment scenes. To address the issues, we have launched a subject recruitment initiative. Our goal is to work in concert with MTFs to establish a broader, far more robust and active recruitment system.
- Navy’s Office of Naval Research refusal to consider omnibus BADER CRADA. The current Navy practice of single CRADAs based on a specific project has put our partners at NMCP and NMCS D at a severe disadvantage in limiting their participation in BADER activities.
- Statement of Work revisions. We have realized that some changes are needed to the Statement of Work to fulfill the needs of the MTFs. We will formally request these changes to the GO through the GOR.
- EACE leadership changes. With the pending retirement of COL Evans, we will work closely with her replacement to establish a working relationship and keep the partnership strong between BADER and EACE.



- Potential shifts in MTF research priority areas. Our MTF representative partners have indicated they may be experiencing shifts in MTF research priority areas. We plan on further exploring this topic with EACE leadership following the retirement of COL Evans. Dr. Stanhope will be attending COL Evans retirement event on November 21, 2013 and has meetings planned with MAJ Owen Hill and COL Mundy.

Over the next quarter, the three recently approved clinical research projects will actively be seeking IRB and HRPO approval with the aim of CY 2013 start date. As reported above, we are awaiting contact from a CDMRP contract specialist in order to move forward with these awards.

As we begin to focus on sustainability efforts, BADER will effectively leverage existing networks and establish new partnerships to identify research teams to seek external funding opportunities for sustainability of the Consortium.

Regular monthly meeting of MTF and BADER personnel will continue and focus on engagement and sustainability efforts of the Consortium. Through these meetings and continued support of the MTF needs, initiative focused teams are forming and evidence of impact and sustainability is mounting.

Having obtained nearly \$4 million in additional external funding and initiated four BADER related, but not BADER funded projects, our omnibus Consortium model is rapidly gaining evidence of success.

We look forward to continuing our work in strengthening orthopaedic rehabilitation research to bring all Wounded Warriors back to optimal function.

## **APPENDICES**

## APPENDIX A:

### **Research Projects:**

#### BADER Funded Projects:

Dingwell, J., and Wilken, J. **“Improving Step-To-Step Control of Walking in Traumatic Amputees”** \$679,300. Sites: University of Texas Austin, Brooke Army Medical Center/Center for the Intrepid.

Davis, I., and Linberg, A. **“Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”** \$708,524. Sites: Spaulding Rehabilitation Hospital, Walter Reed National Military Medical Center.

Grabowski, A., Kram, R., Stephenson, R., Litavish, M. **“Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?”** \$882,827. Sites: Eastern Colorado Healthcare System – Department of Veterans Affairs, Jewell Regional Amputation Clinic.

Linberg, A., Wolf, E., Webster, J., Tulskey, D. **“Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators.”** \$1,529,718. Sites: Walter Reed National Military Medical Center, Hunter Holmes McGuire VA Medical Center.

Tulskey, D., Wolf, E., Wilken, J., Wyatt, M., Bushnik, T., Resnik, L., Latlief, G., Kalpakjian, C., Kisala, P. **“Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma.”** \$1,999,969. Sites: New York University, University of Michigan, Walter Reed National Military Medical Center, Brooke Army Medical Center/Center for the Intrepid, Naval Medical Center San Diego, NYU Langone Medical Center, Providence VA Medical Center, James A. Haley Veterans Hospital, Tampa FL.

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#### BADER Scientific Technical Core Supported projects:

Tulskey, D., Wyatt, M., **“A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma.”** Sites: University of Michigan, Naval Medical Center San Diego, Brooke Army Medical Center/Center for the Intrepid.

#### Externally Funded Projects Supporting BADER Activities or Supported by BADER:

Gillespie, J., et al. **“Rapid Prototyping of Advanced Passive Dynamic Ankle-Foot Orthoses Designs for Wounded Warriors.”** \$3,000,000. Sites: University of Delaware. Funded by: DARPA

Whittelsey, S., Selbie, W.S. **“Development of a Low Cost, Real-time Biofeedback Gait Retraining System”** \$149,995. Funded by: NIH, Phase I – SBIR.

Kaufman, K. **“Comparison of 3-D Gait Analysis Data Across Department of Defense Sites.”** Funded by: Center Rehabilitation Sciences Research (CRSR). Support by Biomechanics Scientific Technical Core.

Deluzio, K.J., Selbie, W.S., **“Statistical Models for Establishing a Control Data set for Biomechanical Gait Analysis”** \$25,000. Natural Sciences and Engineering Research Council of Canada.

Pending Proposals for External Funding Supported by BADER:

Morshed, S., Kaufman, K. **“The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees”** Proposal to CDMRP/PRORP, July 2013.

Judkins, T. **“Development of a Mobile Advanced Real-Time Kinetic System (MARKS) for Balance Rehabilitation.”** Proposal to Department of Defense SBIR, June 2013.

Ziemke, G., Campello, M. **“A pilot study to test the efficacy of psychologically based physical therapy training for treating deployed US Sailors and Marines with musculoskeletal injuries.”** Proposal to CDMRP/PRORP, July 2013.

Van Citters, D. **“Active Implant”** Proposal to CDMRP/PRORP, July 2013.

MTF Research Projects Supported by CRC Staff:

Adaptation Study	WRNMMC	CRC Staff (Saha)
OA Project	WRNMMC	CRC Staff (Saha)
Trunk	WRNMMC	CRC Staff (Saha)
BL	BAMC/CFI	CRC Staff (Jamison)
RE	BAMC/CFI	CRC Staff (Jamison)
AFOR	BAMC/CFI	CRC Staff (Jamison)
RG	BAMC/CFI	CRC Staff (Jamison)
AF	BAMC/CFI	CRC Staff (Jamison)
EACE P2M	BAMC/CFI	CRC Staff (Metzger-Abamukong)
MPL	BAMC/CFI	CRC Staff (Metzger-Abamukong)

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Research Proposals - BADER Supported

Ziemke, G. **“Rate of Surgical Revision in Active Duty Service Members After Anterior Cervical Disc Arthroplasty or Fusion for Spinal Post-Traumatic Osteoarthritis”**. CDMRP/PRORP pre-application, not invited for full submission.

Ziemke, G. **“Identifying Obstacles and Facilitators of Work Re-Integration in Active Duty Sailors and Marines with Deployment and/or Combat-Related Musculoskeletal Injuries.”** CDMRP/PRORP pre-application, not invited for full submission.

Buchanan, T. **“OA study.”** CDMRP/PRORP pre-application, not invited for full submission.

The BADER Consortium Administrative Core supported, at their request, the VA with planning the upcoming, DEKA arm multi-center clinical trial.

The MTF/BADER Consortium limb salvage team submitted an unfunded pre-proposal to the PRORP TRPA program.

Dr. Tim Judkins with Intelligent Automation, Inc. has completed a DoD funded Phase I SBIR, Virtual Therapist PTSD, project and wishes to develop and execute the Phase II, clinical trial effort, through the BADER Consortium.

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## APPENDIX B:

### **BADER Funded Projects**

#### ***Publications:***

None at this time.

#### ***Abstracts:***

- Cusumano, J.P. and Dingwell, J.B. (2013) "On the Role of Perception in Regulating Stride-To-Stride Walking Dynamics," ***Proceedings of the 2013 Dynamic Walking Meeting***, Pittsburgh, PA, June 10-13, 2013.
- Rylander, J.H., Wilken, J.M., Cusumano, J.P., and Dingwell, J.B. (2013) "Coronal Plane Treadmill Stepping Control Strategies in Individuals with Transtibial Amputation," ***Proceedings of the 43rd Annual Meeting of the Society for Neuroscience***, San Diego, CA, November 9-13, 2013.
- Dingwell, J.B., and Cusumano, J.P. (2013) "Using Perceptual Cues to Regulate Walking From Stride-to-Stride," ***Proceedings of the 43rd Annual Meeting of the Society for Neuroscience***, San Diego, CA, November 9-13, 2013.
- Samaan, C., Schwartz, J., Graf, E., Davis, I., and Rainbow, M.J. (2013) "A Standing Alignment System Improves Between-Session Repeatability in gait Kinematics: A Preliminary Study," ***Proceedings of the Annual Meeting of the American Society of Biomechanics***, Omaha, NE, September 4-7, 2013

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#### ***Patents:***

None at this time

### **BADER Supported Projects**

#### ***Publications***

None at this time.

#### ***Abstracts:***

None at this time.



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**Patents:**

None at this time

**BADER Related Projects**

**Publications:**

Takahashi KZ, Kepple TM, Stanhope SJ. A unified deformable (UD) segment model for quantifying total power of anatomical and prosthetic below-knee structures during stance in gait. *Journal of Biomechanics* 2012;45:2662-2667. PMID:22939292

Schrank E and Stanhope SJ. Dimensional accuracy of ankle-foot orthoses constructed by an automated fit customization and rapid manufacturing framework. *Journal of Rehabilitation Research & Development* 2011;48(1):31-42. PMID:21328161

**Abstracts and Presentations:**

- Schrank ES, Higginson JS, Stanhope SJ. A Repeatable and Predictable method to Rapidly Manufacture Function-Customized Passive-Dynamic Ankle Foot Orthoses. **Proceedings of the ASME**, 2012
- Razzook A, Gleason C, Willy R, Fellin R, Davis I, Stanhope S. Average Ankle Dynamic Joint Stiffness During Heel Strike Running. **(Proceedings) American Society of Biomechanics**, 2012
- Takahashi KZ, Stanhope SJ. Net Efficiency of the Combined Ankle-Foot System in Normal Gait: Insights for passive and Active Prosthetics. **(Proceedings) American Society of Biomechanics**, 2012
- Schrank ES, Higginson JS, Stanhope SJ. Compensatory Muscle Control Strategies when Walking with a Customized PD-AFO. **(Proceedings) American Society of Biomechanics**, 2011
- Takahashi KZ, Razzook AR, Guinn LD, Schrank ES, Kepple TM, Stanhope SJ. Unified Deformable Segment Model of the Combined Ankle-Foot System that Does Work. **(Proceedings) American Society of Biomechanics**, 2011
- Guinn LD, Takahashi KZ, Razzook AR, Schrank ES, Stanhope SJ. A proposed method for PD-AFO stiffness prescription procedure. **(Proceedings) Center for Biomedical Engineering Research Symposium**, University of Delaware, 2011.
- Guinn LD, Takahashi KZ, Razzook AR, Schrank ES, Stanhope SJ. Ankle Pseudo-Stiffness is Greatest During Gait Initiation. **(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.

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- Razzook AR, Takahashi KZ, Guinn LD, Schrank ES, Stanhope SJ. Predictive Model for Natural Ankle Stiffness During Walking: Implications for Ankle Foot Orthosis Prescription.  
**(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.
  - Takahashi KZ, Razzook AR, Guinn LD, Schrank ES, Stanhope SJ. A Model of Normal Gait Roll-Over Dynamics One Step Closer to Customizing Prosthetic Ankle-Foot Components.  
**(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.

**Patents:**

None at this time.

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## **APPENDIX C:**

### ***Affiliations:***

#### Government partners:

- CDMRP
- Brooke Army Medical Center
- Naval Medical Center Portsmouth
- Naval Medical Center San Diego
- Walter Reed National Military Medical Center
- National Institutes of Health
- Department of Veterans Affairs
- ECBC/ADM

#### Academic partners:

- University of Delaware
- Spaulding Rehabilitation Hospital
- Mayo Clinic
- University of Texas Austin
- University of Michigan
- New York University
- Christiana Care Health System
- Simbex, LLC

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#### Industry partners:

- C-Motion, Inc
- Independence Prosthetics and Orthotics
- BiOM
- Ossur
- Otto-Bock
- Hanger Orthopedics

#### Non-Profit partners:

- Amputee Coalition
- Agrability

**APPENDIX D:**

***BADER Consortium Affiliates***

Total as of September 30, 2013: 96

<b>Aldridge, Jennifer</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Anne Andrews, LTC, PhD, RD, CSSD, CSCS</b>	BADER Consortium Affiliate, Director of Othopaedic Rehabilitation Research	Walter Reed National Military Medical Center (WRNMMC)
<b>Archer, Kristin R., PhD, PT, DPT</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Vanderbilt
<b>Bonato, Paolo, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Spaulding Rehabilitation Hospital
<b>Brown, Douglas</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS D)
<b>Buchanan, Thomas S., PhD</b>	BADER Consortium Affiliate	University of Delaware
<b>Campello, Marco, PhD</b>	BADER Consortium Affiliate	New York University
<b>Carney, Joseph</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS D)
<b>Casler, Rick</b>	BADER Consortium Affiliate	BiOM
<b>Cella, David, PhD</b>	BADER Consortium Affiliate	Northwestern University
<b>Cesario, Erin</b>	CRC Staff BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS D)
<b>Childs, John D., PT, PhD, MBA</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Dept. of the Army
<b>Collins, John-David</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS D)
<b>Crandell, David, MD</b>	BADER Consortium Affiliate	Spaulding Rehabilitation Hospital
<b>Dankmeyer, Charles H., CPO</b>	BADER Consortium Affiliate	Dankmeyer, Inc.

<b>Davis, Irene Sprague, PhD, PT</b>	Director, Clinical Research - BADER Consortium	Spaulding Rehabilitation Hospital
<b>Davis, Samuel, PhD</b>	BADER Consortium Affiliate	Naval Medical Center Portsmouth (NMCP)
<b>de Lateur, Barbara J., MD, MS</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Johns Hopkins Medicine
<b>DeMaio, Marlene, CAPT</b>	BADER Consortium Affiliate	Naval Medical Center Portsmouth (NMCP)
<b>Dingwell, Jonathan B., PhD</b>	BADER Consortium Affiliate	University of Texas at Austin
<b>Dromsky, David</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS)
<b>Evans, Boyd</b>	BADER Consortium Affiliate	Oak Ridge National Labs
<b>Farrell, Todd R., PhD</b>	BADER Consortium Affiliate	Liberating Technologies, Inc.
<b>Fatone, Stefania</b>	BADER Consortium Affiliate	Northwestern University
<b>Faulkner, Danielle</b>	CRC Staff BADER Consortium Affiliate	Naval Medical Center Portsmouth (NMCP)
<b>Ferguson, John</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Ficke, James R., PhD</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Fitzgerald, G. Kelley, PhD</b>	BADER Consortium Affiliate	University of Pittsburgh
<b>Friedman, Matthew J., MD, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Dartmouth
<b>Gard, Steven A., PhD</b>	BADER Consortium Affiliate	Northwestern University
<b>Gill, Norman "Skip" LTC</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Gillespie, John W., PhD</b>	BADER Consortium Affiliate	University of Delaware
<b>Grabowski, Alena, PhD</b>	BADER Consortium Affiliate	Massachusetts Institute of Technology

<b>Greenwald, Rick, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Simbex
<b>Groer, Shirley, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Department of Veterans Affairs
<b>Hansen, Andrew, PhD</b>	BADER Consortium Affiliate	Department of Veterans Affairs
<b>Hendershot, Brad</b>	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Hicks, Gregory E., PhD, PT</b>	BADER Consortium Affiliate, Research Advisory Committee Member	University of Delaware
<b>Hiebert, Rudi</b>	BADER Consortium Affiliate	New York University
<b>Hopkins, Mark S., PT, CPO, MBA</b>	BADER Consortium Affiliate	Dankmeyer, Inc.
<b>Hsu, Joseph, PhD, LTC</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Jamison, Steve, PhD</b>	CRC Staff BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Jarzombek, Sandi</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Kaufman, Kenton R., PhD, PE</b>	Director, Scientific Cores	Mayo Clinic
<b>Kelley, Kevin</b>	BADER Consortium Affiliate	Ottobock
<b>Kingsbury, Trevor</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS)
<b>Klute, Glenn K., PhD</b>	BADER Consortium Affiliate	University of Washington
<b>Kolm, Paul, PhD</b>	BADER Consortium Affiliate, Director, Biostatistics Core	Christiana Care Health Services, Inc.
<b>Kram, Rodger, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	University of Colorado
<b>Kuiken, Todd, MD, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Rehabilitation Institute of Chicago



<b>Linberg, Alison</b>	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Logerstedt, David, PT, PhD, MPT, SCS</b>	BADER Consortium Affiliate	University of Delaware
<b>Ludewig, Paula M.</b>	BADER Consortium Affiliate	University of Minnesota
<b>Metzger-Abamukong, Melinda</b>	CRC Staff BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Milbourne, Suzanne A., PhD</b>	BADER Consortium Affiliate	University of Delaware
<b>Miller, Ross H., PhD</b>	BADER Consortium Affiliate	University of Maryland
<b>Mulroy, Sara, PhD, PT</b>	BADER Consortium Affiliate	Rancho Los Amigos National Rehabilitation Center
<b>Myers, Grant</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS)
<b>Neptune, Rick</b>	BADER Consortium Affiliate	University of Texas at Austin
<b>Nordin, Margareta</b>	BADER Consortium Affiliate	New York University
<b>Nowinski, Cindy, MD, PhD</b>	BADER Consortium Affiliate	Northwestern University
<b>Owens, Johnny, PT</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Pasquina, Paul, COL</b>	BADER Consortium Affiliate	Uniformed Services University of the Health Sciences
<b>Powers, Christopher M., PhD, PT</b>	BADER Consortium Affiliate	University of Southern California
<b>Rabago, Chris</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Resnick, Linda, PhD</b>	BADER Consortium Affiliate	Brown University
<b>Richards, James G., PhD</b>	BADER Consortium Affiliate	University of Delaware
<b>Ritland, Bradley, CAPT</b>	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)

<b>Rodriguez, Kelly</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Rosenthal, Michael D., CAPT</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS D)
<b>Royer, Todd, PhD</b>	BADER Consortium Affiliate	University of Delaware
<b>Sacher, Richard S</b>	BADER Consortium Affiliate	University of Delaware
<b>Saha, Devjani, PhD</b>	CRC Staff BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Schaffer, Scott, LTC</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Schnall, Barri</b>	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Scoville, Charles</b>	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Selbie, William Scott, PhD</b>	BADER Consortium Affiliate, Director, Biomechanics Core	C-Motion, Inc.
<b>Sessoms, Pinata</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS D)
<b>Shim, Jae Kun, PhD</b>	BADER Consortium Affiliate	University of Maryland
<b>Silverman, Anne</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Sluka, Kathleen A., PT, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	University of Iowa Health Care
<b>Snyder-Mackler, Lynn, PT, PhD, FAPTA</b>	BADER Consortium Affiliate	University of Delaware
<b>Stanhope, Steven J., PhD</b>	Director, BADER Consortium	University of Delaware
<b>Swiontkowski, Marc F., MD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	University of Minnesota
<b>Takahashi, Kota, PhD</b>	BADER Consortium Affiliate	North Carolina State University
<b>Thesing, Nancy</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS D)

<b>Tulsky, David, PhD</b>	BADER Consortium Affiliate, Director, Outcome Measures Core	University of Michigan Medical School
<b>Vernon, Michael</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Ward, Samuel R., PT, PhD</b>	BADER Consortium Affiliate	University of California, San Diego
<b>Weir, Richard, PhD</b>	BADER Consortium Affiliate	University of Colorado
<b>Wilken, Jason, PhD, MPT</b>	MTF Representative	San Antonio Military Medical Center (SAMMC)
<b>Wingate, Amanda</b>	CRC Staff BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Wolf, Erik, PhD</b>	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Wyatt, Marilyn</b>	MTF Representative	Naval Medical Center San Diego (NMCS)
<b>Yack, John</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Ziemke, Gregg, CAPT</b>	MTF Representative	Naval Medical Center Portsmouth (NMCP)

## APPENDIX E

Omnibus BADER CRADA partners:

Institution	Date of distribution	Date of completed agreement
University of Delaware	September 19, 2012	November 7, 2012
Brooke Army Medical Center	September 19, 2012	January 3, 2013
C-Motion, Inc	September 19, 2012	September 20, 2012
Christiana Care Health Systems	September 19, 2012	October 18, 2012
Mayo Clinic	September 19, 2012	November 1, 2012
Spaulding Rehabilitation Hospital	September 19, 2012	October 11, 2012
Walter Reed National Military Medical Center	September 19, 2012	April 15, 2013

### Projects on-boarded to Omnibus BADER CRADA:

Dingwell, J., and Wilken, J. **“Improving Step-To-Step Control of Walking in Traumatic Amputees”** \$679,300. Sites: University of Texas Austin, Brooke Army Medical Center/Center for the Intrepid.

Davis, I., and Linberg, A. **“Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”** \$708,524. Sites: Spaulding Rehabilitation Hospital, Walter Reed National Military Medical Center.

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### Sites and Projects to be on-boarded to Omnibus BADER CRADA:

- Naval Medical Center San Diego
- Naval Medical Center Portsmouth
- Eastern Colorado Healthcare System – Department of Veterans Affairs
- NYU Langone Medical Center
- Providence VA Medical Center
- James A. Haley Veterans Hospital, Tampa FL
- Grabowski, A., Kram, R., Stephenson, R., Litavish, M. **“Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?”**
- Linberg, A., Wolf, E., Webster, J., Tulskey, D. **“Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators.”**
- Tulskey, D., Wolf, E., Wilken, J., Wyatt, M., Bushnik, T., Resnik, L., Latlief, G., Kalpakjian, C., Kisala, P. **“Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma.”**

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## **APPENDIX F**

### *Meetings*

#### Attended

- Amputee Coalition National Conference. Orlando, FL. June 27-29, 2013.
- 2013 AAOS/OTA/SOMOS/ORS Extremity War Injuries VIII: Sequelae of Combat Injuries. February 11-13, 2013 at the Mandarin Oriental Hotel in Washington, DC
- American Society of Biomechanics, Omaha NE, September 4-7, 2013.
  - BADER Consortium funds supported travel for Stanhope, Wilken, Wolf
- 2013 Military Health System Research Symposium, Ft Lauderdale, FL, August 12-15, 2013.
- American Orthotic & Prosthetic Association, O&P World Congress 2013. Orlando, FL, September 18 – 21, 2013.

#### Upcoming

- Government Steering Committee meeting to discuss proposals: Proposed for January or February 2014 at Ft. Detrick MD.
- International State of the Science Meeting on Limb Salvage. January 14-15, 2014.
- WRNMMC Grand Rounds. Erik Wolf at WRNMMC has requested travel support for Dr. Andrew Hansen, VA to present Grand Rounds and discuss research collaborations at WRNMMC.
- Extremity War Injuries Symposium: February 2014

## APPENDIX G

### GSC Meeting Agendas and Attendees

#### Government Steering Committee Meeting - January 12, 2012

**US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND  
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)  
PEER REVIEWED ORTHOPAEDIC RESEARCH PROGRAM (PRORP)**

**BADER CONSORTIUM: GOVERNMENT STEERING COMMITTEE MEETING  
12 JANUARY 2012, FT. DETRICK, MARYLAND**

### AGENDA

<b>7:30 a.m. – 8:00 a.m.</b>	Arrival	All Participants
<b>8:00 a.m. – 8:10 a.m.</b>	Welcome and Introductions	COL Leggit
<b>8:10 a.m. – 8:15 a.m.</b>	Moment of Silence	TBD
<b>8:15 a.m. – 8:45 a.m.</b>	Overview of Today's Meeting	Dr. Darnell
	Roles and Responsibilities for GSC Meeting Participants	Ms. Dellinger Mr. Kelly
<b>8:45 a.m. – 9:15 a.m.</b>	Overview: BADER Consortium	Dr. Stanhope
<b>9:15 a.m. – 9:30 a.m.</b>	Study 1: Bone Health & Function in Transfemoral Amputees	Dr. Kaufman
<b>9:30 a.m. – 9:40 a.m.</b>	Discussion	All Participants
<b>9:45 a.m. – 10:00 a.m.</b>	Study 2: Improving Step-To-Step Control of Walking	Dr. Dingwell
<b>10:00 a.m. – 10:10 a.m.</b>	Discussion	All Participants
<b>10:15 a.m. – 10:30 a.m.</b>	Break	



<b>10:30 a.m. – 10:45 a.m.</b>	Study 3: Enhanced Locomotion for Limb Salvage Patients	Dr. Wilken
<b>10:45 a.m. – 10:55 a.m.</b>	Discussion	All Participants
<b>11:00 a.m. – 11:15 a.m.</b>	Study 4: Returning to High-Level Performance-Training to Run	Dr. Davis
<b>11:15 a.m. – 11:25 p.m.</b>	Discussion	All Participants
<b>11:30 a.m. – 12:00 p.m.</b>	USAMRMC ORP Oversight	Ms. Duchesneau
<b>12:00 p.m. – 1:00 p.m.</b>	Lunch	All Participants
<b>1:00 p.m. – 1:30 p.m.</b>	Initial perspectives on MTFs and Research Implementation Strategies	Dr. Stanhope
<b>1:30 p.m. – 1:45 p.m.</b>	BADER Consortium: Future Study Selection Process	Dr. Davis
<b>1:45 p.m. – 2:45 p.m.</b>	GSC discussion with GOR	GSC membership
	BADER Consortium Pls: Group Discussion at NCI Cafeteria	Consortium Pls
<b>2:45 p.m. – 4:00 p.m.</b>	Strategic planning session <i>Potential topics:</i> <ul style="list-style-type: none"> <li>- <i>Project approval</i></li> <li>- <i>Clinical Based Pathways - Initiative based research</i></li> <li>- <i>Approval to move forward with Spring call for proposals</i></li> <li>- <i>Coordination of multiple Research Programs (AFIRM, METRC, EACE)</i></li> <li>- <i>Moving from reactive to proactive research</i></li> <li>- <i>Identifying subject pools</i></li> </ul>	All Participants
<b>4:00 p.m. – 4:15 p.m.</b>	June GSC planning	All Participants
<b>4:15 p.m. – 4:30 p.m.</b>	Summary and Adjournment	Darnell/Stanhope

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**BADER Government Steering Committee Teleconference Participants (January 12, 2013)**

**BADER Government Steering Committee (GSC) members:**

**Dr. Allison Milutinovich**

PROP Program Manager, CDMRP

**Ms. Juanita (Nita) Grimsley**

USAMRMC Combat Casualty Care Research Program

**LTC David Wright**

USAMRMC Clinical and Rehabilitative Medicine Research Program

**Dr. Kelley Brix**

Office of the Assistant Secretary of Defense

**Dr. Robert Jaeger**

Department of Veterans Affairs

**Dr. Louis Quatrano**

National Institutes of Health

**COL Edward Arrington**

Madigan Army Medical Center

**Dr. Steven Scott**

Department of Veterans Affairs, Tampa

**LTC (P) John Scherer\***

USAMRMC Clinical and Rehabilitative Medicine Research Program

\*Attending in lieu of Lt. Col. Wright (Not a GSC Member)

**BADER Consortium participants:**

**Dr. Steven Stanhope**

University of Delaware

**Dr. Irene Davis**

Spaulding/ Harvard University

**Dr. Kenton (Ken) Kaufman**

Mayo Clinic

**Ms. Rachel Strickland**

University of Delaware

**Dr. Jonathon Dingwell**

University of Texas at Austin

**USAMRMC participants:**

**COL Jeffrey Leggit**

Director, Congressionally Directed Medical Research Programs (CDMRP)

**Dr. Miriam Darnell**

BADER GOR, CDMRP

**Mr. Chris Baker**

USAMRAA

**LCDR Mark Clayton**

CDMRP

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**Ms. Susan Dellinger**

USAMRAA (GO)

**Ms. Caryn Duchesneau**

ORP

**COL Dallas Hack**

CCCRP

**Mr. Jeremiah Kelly**

USAMRMC

**MTF participants:**

**LTC Anne Andrews**

Walter Reed National Military Medical Center

**COL Paul Stoneman**

Walter Reed National Military Medical Center

**Dr. Jason Wilken**

Brooke Army Medical Center, Center for the Intrepid

**COL Rachel Evans**

Brooke Army Medical Center, Center for the Intrepid

**Ms. Marilyn Wyatt**

Naval Medical Center San Diego

**CDR Michael Rosenthal**

Naval Medical Center San Diego

**CAPT Gregg Ziemke**

Naval Medical Center Portsmouth

**Dr. Samuel Davis**

Naval Medical Center San Diego

**Government Steering Committee Meeting - March 18 2013**

**Agenda:**

US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

**CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)**

**PEER REVIEWED ORTHOPAEDIC RESEARCH PROGRAM (PRORP) FISCAL YEAR 2010 (FY10)**

**THE BADER CONSORTIUM**

**GOVERNMENT STEERING COMMITTEE (GSC) MEETING**

**18 March 2013**

**AGENDA**

Teleconference numbers:

DCO Connect: <https://connect.dco.dod.mil/cdmrpteamleader>

Inside the U.S.: 1-800-366-7242

Outside the U.S.: 1-858-826-6707

Conference code: 8389736

8:00 a.m. – 8:05 a.m.	Welcome	CDMRP Leadership
8:05 a.m. – 8:10 a.m.	Moment of silence	LTC Wright
8:10 a.m. – 8:20 a.m.	Introductions Purpose of GSC meeting	Dr. Darnell
8:20a.m. – 9:20a.m.	<u>Progress Report</u> <ul style="list-style-type: none"> <li>• Consortium Cores</li> <li>• Partnerships</li> <li>• CRADA</li> <li>• CTDB</li> <li>• Integration with DoD: MTFs and VA</li> <li>• Sustainability</li> </ul>	Dr. Stanhope
9:20 a.m. – 9:45 a.m.	Discussion	All Participants
9:45a.m. – 10:15 a.m.	<u>Current Studies</u> <ul style="list-style-type: none"> <li>• Step to Step Control clinical trial update</li> <li>• Walk to Run clinical trial update</li> </ul>	Dr. Davis
10:15 a.m. – 10:30 a.m.	Break (reminder to disconnect except Dr. Davis and Dr. Greenwald)	All Participants

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10:30 a.m. – 11:00 a.m.	<u>Study selection process</u> <ul style="list-style-type: none"> <li>• Call for Proposals</li> <li>• Submissions</li> <li>• Peer review and summary statements</li> </ul>	Dr. Davis
11:00 a.m. – 11:30 a.m.	Budgetary and Programmatic Analysis	Dr. Stanhope
11:30 a.m. – 11:45 a.m.	The EACE perspective of current research at MTFs	COL Evans
11:45 a.m. – 12:00 p.m.	Discussion	All participants
12:00 p.m. – 1:00 p.m.	Lunch (on your own)  NCI cafeteria is available for your use.	All participants
1:00 p.m. – 3:00 p.m.	GSC review of proposed research projects (closed GSC session)	GSC Members
3:00 p.m. – 3:10 p.m.	Break	GSC Members
3:10 p.m. – 4:00 p.m.	GSC review of proposed research projects (closed GSC session)	GSC Members
4:00 p.m. – 5:00 p.m.	Discussion to recommend projects for funding (closed GSC session)	GSC Members

### **BADER Government Steering Committee Teleconference Participants (March 18, 2013)**

#### **BADER Government Steering Committee (GSC) members:**

**COL Rachel Evans**

Center for the Intrepid, San Antonio Military Medical Center, EACE

**Ms. Nita Grimsley**

USAMRMC Combat Casualty Care Research Area Directorate,

**Dr. Robert Jaeger**

Department of Veterans Affairs

**COL Martha Lenhart**

USAMRMC JPC-1 Medical Training and Health Information Sciences Research Program

**Dr. Steven Scott**

Department of Veterans Affairs, Tampa

**Col Linda Steel-Goodwin**

Office of the Assistant Secretary of Defense, Health Affairs

**Dr. Louis Quatrano**

National Institutes of Health

**LTC David Wright**

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USAMRMC Clinical and Rehabilitative Medicine Research Area Directorate

**Dr. Joseph Wenke (ad hoc participant)**

US Army Institute of Surgical Research

**BADER Consortium participants:**

**Dr. Steven Stanhope**

University of Delaware

**Dr. Irene Davis**

Spaulding/ Harvard University

**Dr. Rick Greenwald**

Dartmouth College

**Dr. Kenton (Ken) Kaufman**

Mayo Clinic

**Ms. Rachel Strickland**

University of Delaware

**Dr. Alison Linberg**

Walter Reed National Military Medical Center

**Dr. Jason Wilken**

Brook Army Medical Center

**Ms. Marilyn Wyatt**

Naval Medical Center San Diego

**CAPT Gregg Ziemke**

Naval Medical Center Portsmouth

**USAMRMC participants:**

**COL Jeffrey Leggit**

Director, Congressionally Directed Medical Research Programs (CDMRP)

**Dr. Miriam Darnell**

BADER GOR, CDMRP

**Dr. Allison Milutinovich**

PRORP Program Manager, CDMRP

**Ms. Dana Herndon**

US Army Medical Research Acquisition Activity (USAMRAA)

**Ms. Amanda Sachtleben**

Office of Research Protections



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## APPENDIX H

*BADER Annual Meeting: WARRIOR Summit*

*July 12, 2013*

*Center for the Intrepid, Brooke Army Medical Center, Ft. Sam Houston TX*

Agenda and Attendees:

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## BADER Consortium - 2013 Annual Meeting

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### **WARRIOR (WARfighters Receiving Innovative Orthopaedic Rehabilitation) Priorities Meeting**

#### **Meeting Objective**

*The overall goal of this meeting is to develop an overall research plan that addresses the DoD identified research gaps and further promote collaborations between the BADER Consortium partners.*

#### **Meeting Location**

Center for the Intrepid, Brooke Army Medical Center, Ft. Sam Houston, TX

#### **Meeting Date**

June 12, 2013

0800-1530 CDT

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#### **Meeting Outline**

- 1) Call to Order (10 minutes) **0800-0810 LTC Gajewski**
  - a) Greetings
  - b) Moment of Silence
- 2) Welcome and Introduction (15 minutes) **0810-0825 Dr. Steven Stanhope**
  - a) Meeting goals
  - b) Packet materials
  - c) Review of agenda
- 3) EACE (20 minutes) **0825-0845 COL Evans**
  - a) Mission
  - b) Goals
  - c) Current activities
- 4) BADER Consortium Research Directions (15 minutes) **0845-0900 Dr. Irene Davis**
  - a) Current Research Projects
  - b) Projects funded by most recent Call for Proposals
- 5) DOD Rehabilitation Research (20 minutes) **0900-0920 COL Evans**

- a) Present current research gaps identified by Clinical and Rehabilitation Medicine Research Area Directorate
- b) Review ongoing research in each of the gap areas
  - i) at each of the MTFs
  - ii) outside the MTFs

\*\*\*\*BREAK\*\*\*\* 0920-0950

- 6) Develop BADER Consortium research initiatives in identified gaps which are not currently being addressed (90 minutes) **0950-1120 Dr. Davis**
- 7) Prioritize BADER Consortium research initiatives (20 minutes) **1120-1140 Dr. Davis**

\*\*\*\*TOUR CFI\*\*\* 1140-1200

\*\*\*\*LUNCH\*\*\*\* 1200-1300

- 8) BADER Call for proposals (30 minutes) **1300-1330 Dr. Davis**
  - a) Gap areas to be solicited
  - b) Funding available
  - c) Mechanism
  - d) Timeframe
- 9) Capabilities required to advance research program (30 minutes) **1330-1400 Dr. Kaufman**
- 10) Research Support for Gaps not covered by Call for Proposals (60 minutes) **1400-1500 Dr. Stanhope**
- 11) Wrap-up (30 minutes) **1500-1530 COL Evans & Dr. Stanhope**

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<b>Dr. Timothy Brindle</b> Scientific Program Manager Musculoskeletal and Medical Comorbidity Rehabilitation Research and Development Veterans Health Administration	<b>Dr. Paul Kolm</b> Director, Biostatistics Core BADER Consortium Center for Outcomes Research Christiana Care Health Services, Inc.
<b>Ms. Erin Cesario</b> Protocol and Data Management Coordinator BADER Consortium Clinical Research Core Naval Medical Center San Diego	<b>Dr. Rodger Kram</b> Chair, Research Advisory Committee BADER Consortium Department of Integrative Physiology University of Colorado
<b>Dr. Miriam Darnell</b> <i>(Attending Remotely)</i> Science Officer for Grants Management Grant Officer's Representative (GOR) Congressionally Directed Medical Research Programs	<b>Ms. Melinda Metzger-Abamukong</b> Protocol and Data Management Coordinator BADER Consortium Clinical Research Core Brooke Army Medical Center Center for the Intrepid

<b>Dr. Irene Davis</b> Co-PI, BADER Consortium Director, Spaulding National Running Center Department of Physical Medicine and Rehabilitation Harvard Medical School Spaulding-Cambridge Outpatient Center	<b>Dr. Suzanne Milbourne</b> Acting Manager, Clinical Research Core BADER Consortium Kinesiology and Applied Physiology University of Delaware
<b>COL Rachel Evans</b> Research Director Director of Orthopaedic Rehabilitation Research Brooke Army Medical Center Center for the Intrepid	<b>Dr. Allison Milutinovich</b> <i>(Attending Remotely)</i> PRORP Program Manager Congressionally Directed Medical Research Programs
<b>Ms. Danielle Faulkner</b> Protocol and Data Management Coordinator BADER Consortium Clinical Research Core Naval Medical Center Portsmouth	<b>Dr. Grant Myers</b> Research Associate BADER Consortium Clinical Research Core Naval Medical Center San Diego
<b>Mr. Rudi Hiebert</b> Research Associate BADER Consortium Clinical Research Core Naval Medical Center Portsmouth	<b>CAPT Michael Rosenthal</b> <i>(Attending Remotely)</i> MTF Representative Naval Medical Center San Diego
<b>Dr. Robert Jaeger</b> <i>(Attending Remotely)</i> BADER Consortium GSC Director, Development Health Research Veterans Health Administration	<b>Dr. Richard Sacher</b> Information Tech. Infrastructures Office BADER Consortium Assoc Dir, Rsrch Data Mgmt, IT-Client Support & Services Associate Professor, Mathematical Sciences University of Delaware
<b>Dr. Steve Jamison</b> Research Associate BADER Consortium Clinical Research Core Brooke Army Medical Center Center for the Intrepid	<b>Dr. Devjani Saha</b> Research Associate BADER Consortium Clinical Research Core Walter Reed National Military Medical Center
<b>Dr. Kenton R. Kaufman</b> Co-PI, BADER Consortium Professor of Biomedical Engineering Departments of Orthopedic Surgery, Physiology and Biomedical Engineering, and Biomechanics and Motion Analysis Lab Mayo Clinic	<b>Dr. William Scott Selbie</b> Director, Biomechanics Core BADER Consortium C-Motion, Inc.
<b>Dr. Steven Stanhope</b> PI, BADER Consortium	<b>Ms. Rachel Strickland</b> Director, BADER Administrative Core

<p>Professor, Kinesiology and Applied Physiology Biomechanics and Movement Sciences (MIOMS) Interdisciplinary Program Mechanical Engineering University of Delaware</p>	<p>BADER Consortium Kinesiology and Applied Physiology University of Delaware</p>
<p><b>Dr. David Tulskey</b> Director, Outcome Measures Core BADER Consortium Dept. of Physical Medicine &amp; Rehabilitation University of Michigan Medical School</p>	<p><b>Dr. Jason Wilken</b> Director, Military Performance Lab MTF Representative Brooke Army Medical Center Center for the Intrepid</p>
<p><b>Ms. Amanda Wingate</b> Protocol and Data Management Coordinator BADER Consortium Clinical Research Core Walter Reed National Military Medical Center</p>	<p><b>Dr. Erik Wolf</b> MTF Representative Walter Reed National Military Medical Center</p>
<p><b>Ms. Marilyn Wyatt</b> MTF Representative Director, Gait Analysis Laboratory Naval Medical Center San Diego</p>	<p><b>CAPT Gregg Ziemke</b> <i>(Attending Remotely)</i> MTF Representative NMCP Physical Therapy NMCP Spine Center Naval Medical Center Portsmouth</p>

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**APPENDIX I**

**BADER Consortium Committee Memberships**

**BADER Consortium Coordinating Center (B3C) Committee**

Steven J. Stanhope, PhD

Irene Davis, PhD

Kenton Kaufman, PhD

Suzanne Milbourne, PhD

Rachel Strickland

**BADER Consortium Committee (BCC)**

Steven J. Stanhope, PhD

Irene Davis, PhD

Kenton Kaufman, PhD

Suzanne Milbourne, PhD

Rachel Strickland

Jason Wilken, PhD

Marilynn Wyatt

CAPT Greg Ziemke

Alison Linberg, DPT

Jonathan Dingwell, PhD

Scott Selbie, PhD

David Tulskey, PhD

Paul Kolm, PhD